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The Effects of Diabetes Self-Care Management Education Paired with Behavior Change Support Program Using Mobile Technology in Improving Disease Knowledge, Self-Care Activities, and Health Outcomes in Adult Type II Diabetes

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THE EFFECTS OF DIABETES SELF-CARE MANAGEMENT EDUCATION PAIRED WITH BEHAVIOR CHANGE SUPPORT PROGRAM USING MOBILE TECHNOLOGY IN IMPROVING DISEASE KNOWLEDGE, SELF-CARE ACTIVITIES, AND HEALTH OUTCOMES IN ADULT TYPE II DIABETES

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Abstract

Background: Research has shown that Diabetes Self-care Management Education (DSME) paired with the Behavioral Changes Support Program using Mobile Technology (BCSP-MT) has improved patient outcomes by promoting self-care activities. Yet, not many primary practices provide BCSP-MT to improve diabetes care.

Objectives: The study aimed to assess the effectiveness of DSME paired with BCSP-MT in adult type 2 diabetes patients to improve diabetes knowledge, self-care practices, and diabetes control in a primary care setting.

Methods: In this quality improvement project, a 3-months, one-arm, pre-post pilot study was conducted in a clinic, the Northeastern U.S. A convenient sample of 14 people with diabetes with A1C above 7% was recruited. The intervention consisted of 3 weekly educational texts, 2 meetings, and 3 monthly phone calls between the DSME. The outcomes were measured by paired t-test on biometric data (BMI, BP, A1C, & LDL), the Diabetes Knowledge, and Self-Care Activities scores at 3-month marks.

Results: 11 people had reductions in a BMI, A1C, LDL (-0.08, -0.19, -4.45). Considerable improvement in both knowledge (p=.041) and self-care activities scores (p=.19) were noted in the diet, foot care, and exercise in 7 people. Marital status, race, age, and education levels had a significant effect on the completion of the program.

Conclusions: Biometrics, diabetes knowledge and self-care activities were improved after BCSP-MT. Demographic factors should be considered when planning future practice for quality improvement in diabetes care. Further research on a larger sample with a randomized control and 3- to 6-months intervals would increase the cogency of the study.

Introduction

During the past few decades, researchers studied the effectiveness of Diabetes self-management education (DSME) and found a greater reduction in Hemoglobin A1C (A1C) ranging -0.4 to -1.4% at six months following education (Golden et al. 2017). Also, the findings showed a great extent of improvement in knowledge, self-management behavior, self-efficacy, and patient satisfaction. Even though DSME related to lifestyle/health behaviors may affect cost savings and health benefits for diabetes, "strictly educational or focus largely on 'you should' approaches are ineffective or insufficient in promoting behavior change" (Hood. et al., 2015, p.4). Because education alone is insufficient in promoting behavior change, DSME has shifted to DSME paired with mobile technology such as telephone calls or texting to encourage the maintenance of healthy diabetes-related behavior change (Hood et al., 2015; Pillay et al., 2015).

Many studies were conducted on DSME tailed with Behavior Change Support Program using Mobile Technology (BCSP-MT) to provide information on diabetes, healthier lifestyle tips, diet, and exercise to improve self-care management (Dobson et al., 2015; Pillay et al., 2015). Self-Management Support for Blood Glucose Program (SMS4BG) or a texting program showed a reduction in participants' average blood glucose level, A1C levels (avg 0.4), weight (1.3-1.68kg), and daily energy intake (64-13x0050 kilocalories per day) (Dobson et al., 2015; Pillay et al., 2015). Despite the evidence showing that the implementation of BCSP-MT improves patient outcomes and promote long-lasting self-care activities in a primary care setting, this program has not been adopted in the student-investigator's practice setting.

Background and Significance

According to the 2017 National Diabetes Statistic Report, diabetes is more prevalent among minority populations, affecting 15.1% of American Indians/Alaska Native, 12.7% of non-Hispanic blacks, 12.1% of Hispanics, 7.4% of non-Hispanic whites, and 8% of Asians. Diabetes is a complex chronic disease that can result in significant micro- and macro-vascular complications. Unmanaged diabetes can cause serious health complications such as coronary artery disease, stroke, neuropathy, nephropathy, or retinopathy. Irene et al., (2000) reported that the risk of microvascular complications could be reduced by 41%, with each 1% reduction in A1C in people with diabetes while the risk of myocardial infarction would be reduced by 14%. In order to prevent long term complications, patients with diabetes must have a strict adherence to diabetic treatment therapy and life-long management (Hood et al., 2015). However, comprehensive diabetes care management in the primary care setting is challenging due to the continuous care management process, lack of communication, and support needs for patients.

The total cost of diagnosed diabetes in the US in 2017 was $327 billion, and the average medical expenditures among people with diagnosed diabetes were 2.3 times higher than a person without diabetes (American Diabetes Association [ADA], 2018). Hirsch et al. (2017) studied the cost-effectiveness and cost-benefit of collaborative diabetes intensive medical management compared to usual primary care provider (PCP) care, and they found that the medical cost avoidance due to improved A1C was $8,793 per collaborative diabetes intense medical management patient versus $3,506 per PCP patient. Researchers concluded that providing personalized care improved glycemic control, produced a greater cost avoidance, and reduced long-term complication risk (Hirsch et al., 2017).

DSME with an ongoing self-directed behavior change support model does not “focus on success or failure, but the learning that occurs as a result of the experiment… to gain insight into

the barriers and supports they have and their need to make behavioral changes and ultimately to improve their ability to manage their diabetes" (Funnell, Tang, & Anderson, 2007, p, 221). Literature review findings support the implementation of BCSP-MT for text messaging and phone call coaching because the results showed greater improvement in A1C, weight, lipid profile, physical activity, and diabetes self-care behaviors (Agboola et al., 2016,; Andrews et al., 2011; Capozza et al., 2015; Griffin et al., 2014; Nundy et al., 2014; Lari, Noroozi, & Tahmasebi, 2018). A few examples of Care4life text message program from Capozza and his colleagues' study include "No one manages diabetes perfectly. It is a learning process. Learn more about the causes & symptoms of high blood glucose…," "Instead of mayonnaise, spread mustard or avocado on your sandwich for more favor & less fat," and "try to exercise at least 5 days each week unless your doc has told you not to. Reply with the number of days you will exercise this week" (2015, p. 87). Moreover, the participants reported higher satisfaction of the BCSP-MT compared to groups who received only DSME.

This project's goal was to provide the DSME paired with ongoing BCSP-MT for phone call coaching and text messaging to improve patient's knowledge, self-management behavior, and self-efficacy for adult diabetes' maintenance of health, diabetes-related behavior changes at the local level. Unlike usual PCP visits and the DSME alone, the study participants who receive DSME paired with BCSP-MT could receive support for long-lasting diabetes-related behavioral changes toward a healthier life as well as their outcomes. BCSP-MT included educational materials on general diabetes information, healthier lifestyle, medication adherence, and preventative screening for diabetes and delivered by text messages and phone calls. The goal of this project was to implement strategies developed by Dobson et al. (2015) and Pillay et al.

(2015) to reduce A1C and LDL levels in patients who received the DSME tailed with BCSP-MT in a minority focused primary care setting.

Needs Assessment

A strength, weakness, opportunities, and threat (SWOT) analysis was conducted to assess the current organizational situation and determine strategies to move forward for improving diabetes self-care management while also meeting the Triple Aim (see Appendix A for SWOT analysis). Organizational facilitators to the successful implementation of the Doctor of Nursing Practice (DNP) project included having a supportive leadership team and colleagues for diabetes care management improvement. The leadership team values individual employees and supports leadership development and professional growth. The leadership team was already aware of issues on diabetes management and encouraged providers and other medical staff members to participate in the quality improvement process. The organization leadership team and employees shared ideas and evidence-based research findings to make strategies to implement Evidence-Based Practice (EBP) to improve diabetes care. The greatest opportunity for the organization was a collaboration with community health professionals, such as a pharmacist, to provide additional support for the project team and patient education. Several organizational barriers to the successful implementation of the project were identified. The biggest weakness was that only the registered dietitian contractor, who comes once a month, was involved in DSME. At the same time, many other competitors in Montgomery County provided diabetes education programs by certified diabetes educators.

This could be turned into the greatest opportunity for the clinic for leadership development and professional growth. By supporting employees to become a certified diabetes

educator, employees could become a part of the project team and provide evidence-based patient education during the monthly DSME classes. At the time of the DNP project, the DSME class attendee's diabetes control or improvement in self-management was not closely monitored. What was worse, the organization did not provide ongoing BCSP for the DSME attendees. Those identified barriers in diabetes management could be improved by the project team's continuity of care through ongoing, open communication.

One obstacle for this research was that some patients were not eligible to receive free medications and medical equipment because they were non-Montgomery County residents. Low-income, uninsured non-Montgomery County residents must purchase their medications and supplies out-of-pocket, which could negatively impact their adherence to the intervention, the patient outcomes, and could influence withdrawal from the study.

Problem Statement

Comprehensive diabetes care management in the primary care setting is challenging due to the continuous care management process, lack of communication, and support needs for patients. A needs assessment conducted at the Community Medical Clinic in Silver Spring, Maryland, raised concerns about the need to implement evidence-based interventions to improve the quality of care management for diabetes and promote continuous self-management behavior change. The clinic served a large, culturally diverse patient population of mostly South Asian and African immigrants who live in Montgomery County, Maryland. As mentioned above, both ethnic groups have higher rates of diabetes compared to other ethnic groups. The most noticeable issues with the clinic population were that patients were likely to have either uncontrolled or newly diagnosed diabetes due to non-adherence to self-management or unfamiliarity of

preventative care. Indeed, the providers had encountered a high number of adult patients with diabetes who consistently need advice for a healthier diet, a healthier lifestyle, and strict adherence to their medication regimen. While the clinic provides monthly diabetes classes for patients, the clinic did not have methods of following up on an individual's diabetes control or the impact of the DSME on behavior changes. Furthermore, the attendance rate was low, and providers were most likely not aware of which patients are attending the class. Most importantly, the institution did not provide BCSP for continuous diabetes-related behavioral changes. The project was to implement the DSME paired with BCSP-MT and evaluate its effectiveness in improving clinical outcomes and positive self-care behavior changes among underserved patients with diabetes.

Purpose Statement

The purpose of this study was to assist adult type 2 diabetes patients to gain health information, disease management knowledge, and self-care practices through ongoing BCSP-MT. Therefore, individuals could have better self-care behaviors, disease knowledge, and diabetes control with a greater reduction in Body Mass Index (BMI), Blood Pressure (BP), A1C, and Low-Density Lipoprotein (LDL) levels at three-month marks.

BCSP-MT was developed to provide educational materials to promote self-care behaviors that meet parts of the Healthcare Effectiveness Data and Information Set (HEDIS) and the American Diabetes Association's (ADA) guidelines. HEDIS-like comprehensive diabetes management includes having a good A1C control (< 8%), BP control (< 140/90) and the ADA recommended better control of LDL levels (< 100) and lifestyle modification by providing health information and self-care practices (National Committee for Quality Assurance, n.d; ADA,

2004). Unlike the usual diabetes care, the intervention group received ongoing BCSP-MT to support long-lasting diabetes-related behavioral changes toward improved health outcomes. For instance, two to three text messages per week, monthly phone calls, and in-house group meetings over three months were utilized. Evidence-based educational materials were developed using various resources from professional organizations such as the ADA, the National Institutes of Health (NIH), and the Joslin Diabetes Center (JDC). The content of weekly education initiatives was different, including general diabetes education, recommended physical activity, dietary change, medication adherence, and preventative screening for diabetes. The expected outcomes of the experimental group were a reduction in BMI, BP, A1C, and LDL levels and improvement in the diabetes self-care activities and knowledge scores. Baseline data and post-intervention outcomes of the intervention group were compared to find the effectiveness of BCSP at the end of the project.

Practice Question

In adult patients with type II diabetes with A1C 7.0 % or above, how effective is the evidence-based DSME tailed with BCSP-MT in gaining disease management knowledge to promote self-care behaviors and controlling diabetes with a greater reduction in BMI, BP, A1C, and LDL levels at three months marks within a primary care setting?

Aims and Objectives

Aim

The study aimed to assist type 2 diabetes patients to improve clinical outcomes, disease knowledge, and positive self-care practices through patient-centered, evidence-based DSME with added BCSP-MT within a primary care setting.

Objectives

The overall objectives of DSME paired with BCSP were to provide continuous care through mobile communication and education, teaching self-care behaviors, and preventative screening to improve clinical outcomes.

The first objective was to identify the effectiveness of DSME paired with BCSP-MT in improving clinical outcomes toward HEDIS-like measures and the ADA guidelines such as reduction of A1C (<7%), BMI, BP (<140/90), and LDL levels (<70) by comparing pre-post intervention data at three months of implementation (January 2020).

The second objective was to achieve at least a 20% increased score on the Michigan Diabetes Research and Training Center's Diabetes Knowledge Test (RDKT) and The Summary of Diabetes Self-Care Activities Measure (SDSCA) in the intervention group by January 2020.

Review of Literature

Literature reviews were conducted on the effectiveness of the evidence-based DSME with added BCSP-MT in type 2 diabetic patients. The experimental and non-experimental articles were retrieved from PubMed and Scopus databases using the terms "diabetes," "self-management," "behavior change support," and "mobile technology." The search criteria were limited to men and women with type 1 or 2 diabetes age over 18 years, intervention delivered in an outpatient setting, and literature published after 2010. A few articles were also selected during the cross-referencing and were included as eligible evidence studies. A total of eleven studies were selected for review. Considering the quality of evidence, the Johns Hopkins Nursing Evidence-Based Practice Evidence Level and Quality Guide (JHNEBP-L&Q) was used to rate the evidence levels and the quality of studies (Dearholt & Dang, 2018). In this guide, level I

indicated the highest level of evidence, and level V indicated the lowest level of evidence. During the quality of individual evidence appraisal, it was identified that there were five Level l, three Levels II, and three Level III evidence studies with high to good quality of evidence. The high quality of evidence supports the implementation of findings into practice (see Appendix 7 for evidence table).

Five of Level l evidence studies with high to good quality include article numbers 1, 2, 3, and 5 (please refer to Appendix 7). Those randomized controlled trials (RCTs) compare the effectiveness of added BCSP-MT in diabetes to a control population with usual care. Observable measures included A1C, weight, BP, lipid profile, physical activity, dietary change, diabetes self-care behaviors, and patient's perception of usability or satisfaction with the program. Dobson et al. (2018) concluded that the reduction in A1C at nine months was significantly greater in the intervention group (mean −8.85 mmol) than in the control group (mean -3.96 mmol). Significant improvements were also seen for diabetes self-care behaviors such as foot care ($P<0.001$), overall diabetes support ($P=0.03$), health status ($P=0.03$), and perceptions of illness ($P=0.04$) in the intervention group (Dobson et al., 2018). Participants showed high levels of satisfaction with the text messaging program. For instance, 95% of participants reported that the program was useful, and 97% were willing to recommend the program to other people with diabetes (Dobson et al., 2018). Similar to their findings, other Level l evidence outcomes were consistent. Overall, there were increased physical activity, decreased A1C, and bodyweight with high satisfaction of the program in intervention groups (Agboola et al., 2016; Andrews et al., 2011; Capozza et al., 2015; Griffin et al., 2014). Unlike other RCTs, Andrews et al. (2011) used monthly nurse support and a pedometer-based activity program as BCSP. They found improvement in insulin resistance and concentrations of HDL cholesterol and triglycerides in all treatment groups.

However, the improvement was greater in the intensive diet and activity group than in the intensive diet group alone at 6 and 12 months of intervention.

Three studies provided level II evidence, including article number 4, 7, and 9. The high-quality quasi-experimental studies investigated the effectiveness of a short message service (SMS) in diabetes self-care related behavior changes, physical activity, the satisfaction of the program, and health outcomes such as A1C, lipid profile, and BP. Their findings were consistent with research outcomes from Level I evidence. Nundy et al. (2014) found a significant reduction in A1C in poorly controlled diabetes. The average A1C decreased from 10.3% in the pre-period to 8.5 % in the post-period (p= 0.01). There was no change in A1C in the control group. Diabetes Self-Care Activities were improved; following a healthy eating plan that increased from 4.5 days to 5.2 days per week (p =0.03), the number of days of blood glucose monitoring rose from 4.3 days to 4.9 days (p = 0.03), and the number of days of foot care practicing increased from 3.6 days to 4.3 days (p = 0.01). Furthermore, adherence to diabetes medication increased from 83% to 91% (p=0.003) and most participants reported that phone calls from the nurse were helpful for disease-related self-care education. Lari, Noroozi, & Tahmasebi (2018) found that SMS group perceived significantly greater self-efficacy (P = 0.001) and family support (P = 0.046) of physical activity while the perceived barriers (P < 0.001) were significantly lower than the control group. After three months of training, the SMS group had better physical activity performance than the control group (P < 0.001). Dobson et al. (2015) conducted a non-randomized pilot study with the mixed-method design, with A1C as a quantitative measure. For qualitative measures, phone interviews were conducted for patient satisfaction and perceptions of the usability of the Text Message Self-Management Support Program (SMS4BG). At three months, the intervention group had a significant decrease in A1C from baseline, and 93% of

participants reported that the SMS4BG to be useful, as well as positively impacted on the individual's diabetes-related health behaviors.

Three qualitative studies (article # 8, 10, and 11) provided level III evidence (See Appendix 7). The exit interview after four weeks of the mobile phone-based diabetes program showed a reduction in denial of diabetes and reinforcement of the self-management, as well as self-efficacy (Nundy et al., 2013). Penn et al. (2013) and Simon et al. (2018) conducted semi-structured interviews using either face-to-face or telephone after completion of the experimental studies. Penn et al. (2013) analyzed participants' perspectives across different phases, such as initiating, enacting, and maintaining of the behavioral change process. Across all phases, intentions and goal-setting were dominant themes for the behavior change process, while reinforcement, regulation, and decision processes were found more in the maintenance phase. The analysis showed that the individual's social influences, social role, and identity were important because those features could highly motivate people to maintain behavior change, such as physical activity and dietary intake. In Simon and his colleagues' qualitative study, (2018), researchers used the self-determination theory to identify and describe the patient experience for those who participated in the diet, or diet plus physical activity versus usual care RCT (article #2 in table X). In that study, researchers compared outcomes of the control group, diet regimen with a monthly nurse support group, and plus a pedometer-based activity program group (Andrew et al., 2011). Participants with relatively dominant controlled motivation were more likely to comply with the lifestyle recommendations and experience initial behavior change. Still, they often experienced internal conflict, frustration, and a need for continual external prompting (Simon et al., 2018). (See Appendix 7)

Literature reviews of articles with Level I to III evidence showed consistency across findings such as improvement in A1C, weight, lipid profile, physical activity, and diabetes self-care behaviors with high satisfaction of the BCSP-MT for text messaging and phone call coaching (Agboola et al., 2016; Andrews et al., 2011; Capozza et al., 2015; Griffin et al., 2014; Nundy et al., 2014; Lari, Noroozi, & Tahmasebi, 2018). Also, the intervention groups perceived greater reinforcement of self-management and self-efficacy, which could promote physical activities while their perceived barriers were significantly lower than the control group (Lari, Noroozi, & Tahmasebi, 2018; Nundy et al., 2013). The high quality of evidence and consistency across findings support the implementation of these findings into practice.

Based on the literature, BCSP must be developed to provide educational materials to promote self-care behaviors to meet parts of the HEDIS and ADA guidelines, including A1C < 8%, BP < 140/90, LDL < 100, and lifestyle modifications (NCQA, n.d.; ADA, 2004).

EBP Translation model

The Iowa Model of Evidence-Based Practice to Promote Quality Care is an organizational and collaborative model that incorporates past and current research findings to improve the quality of care (Titler, 2007). It has been extensively used in EBP because it focuses on knowledge- and problem-focused triggers in current practices to improve patient care (Doody & Doody, 2011). The Iowa Model provides a step-by-step guide and systematically putting EBP into action.

The Iowa model has seven steps to follow: 1) selection of a topic for evidence-based practice, 2) forming a team responsible for the development, implementation, and evaluation. 3) evidence retrieval to identify available sources, 4) grading the evidence to ensure the strength of

the body of evidence, 5) developing an EBP standard and recommendations for practice, 6) implementing EBP supported by written policy, procedures, and guidelines, and lastly 7) evaluation of EBP initiative from a comparison of a baseline data before and after implementation, audits, and feedback (Doody & Doody, 2011). The organizational approach of the Iowa model can assist the integration of the best research evidence with clinical expertise to promote the quality of care and patient outcomes (Titler et al., 2001).

1. Selection of a topic:

A problem-focused trigger was used to identify the topic. In 2018, the QAI team and the clinical leaders at the clinic were concerned about the quality of diabetes care management and patient outcomes. They were also concerned with incurring a financial burden related to losing county grants as result of the underperformance on diabetes care management measures. The medical director recognized the need for improving diabetes care and agreed to supervise the project team. After considering the evidence, the project topic was selected to find the effectiveness of the evidence-based DSME with added BCSP-MT in type 2 diabetic patients. Diabetic patients who received ongoing BCSP-MT were expected to gain health information, disease management knowledge, and self-care practices. Thus, they could have better self-care behaviors and diabetes control.

2. Forming a team for development, implementation, and evaluation

A team was formed, including interdisciplinary stakeholders. The initiative team members include 1) the DNP student was responsible for texting and calling each participant in an intervention group as a project manager, 2) the medical director supervised the project team, 3) medical assistants (MA) called patients to remind DSME classes, measured and recorded BMI

and BP in eCW, and 5) the quality assessment and improvement (QAI) manager was responsible for retrieving data.

3. Evidence retrieval

As discussed in the literature review section, a comprehensive literature search was performed, and 11 research articles were retrieved from multiple databases by the DNP student.

4. Grading the evidence

The JHNEBP-L&Q was used to rate the evidence levels and the quality of studies. As discussed in the literature review section, the evidence is consistent and has high quality supporting its implementation into practice.

5. Developing an evidence-based practice standard

After assessing the evidence, EBP standards were developed based on the quality and strength of evidence considering its relevance for practice. Based on the literature, the intervention group received ongoing BCSP-MT to support long-lasting diabetes-related behavioral changes with education materials and ongoing support. BCSP was delivered by two to three text messages per week, monthly phone calls, and in-house group meetings between monthly DSME class over three months. Another recommendation for the clinic was to develop BCSP-MT, providing educational content to promote self-care behaviors that meet the HEDIS and ADA. As noted by Lari, Noroozi, & Tahmasebi (2018) and Nundy et al. (2013), with continuous communication and support, the intervention group was expected to have more considerable reinforcement of the self-management and self-efficacy which can promote diabetes-related behavior changes. Expected clinical outcomes are a reduction in BMI, BP, A1C, and LDL levels over three months.

6. Implementing EBP

The evidence-based study protocols were introduced to the clinic. To ensure effective implementation, the project team had a 30-minute meeting to discuss new protocols regarding diabetes care management, especially for BCSP-MT before the implementation. MAs received general instructions and protocols for biometric measurements, follow-up calls, and data recording while ensuring participant's privacy. Providers and other medical staff were informed about the BCSP program and how to refer the eligible patients to the project team. After data analysis and study evaluation, the project team shared the final project results, initiative activities, and the areas of improvement for diabetes comprehensive care during the monthly staff meeting in March 2020. Identifying significant improvements in diabetes patients' clinical outcomes created a sense of rewarding for employees who were involved in the project can motivate staff members to build the momentum of change (Bolman & Deal, 2013, AHRQ, n.d.).

Continuous monitoring of the results from the change was essential in identifying opportunities for improvements in achieving a long-term change (AHRQ, n.d.). The QAI team continuously monitored the comprehensive diabetes measures and analyzed providers' performance to reinforce an individual's performance to sustain changes.

7. Evaluation

As listed under the objectives, the effectiveness of DSME paired with BCSP-MT was evaluated by improved clinical outcomes, including a reduction of A1C, BMI, BP, and LDL levels from their baseline by three months of implementation. The secondary outcomes were to achieve at least a 20% increased score on the DKT and the. The study group's biometric changes, the self-care activities measures, and the knowledge scores were compared from the baseline data to post-intervention outcomes at the end of the study.

Methodology

Setting

A three months, one-arm, pre-post pilot study of BCSP-MT was conducted at the community clinic in the Northeastern U.S. The clinic delivered high-quality, patient-centered medical care for low-income, uninsured residents of Montgomery County, Maryland. The major clinic's population were immigrants from South Asia and Africa who are unfamiliar with getting preventative healthcare. Patient population data were obtained by interviewing an Administrative Chief Executive Officer. Female patients accounted for 64% of the clinic's population. Considering population age, approximately 18% of the population was under 40; 22% are between 40 and 50, while the majority of the population (60%) aged between 60 to 85 years. The clinic addressed prevalent health issues in the U.S. population by providing medical management for chronic diseases such as hypertension, hyperlipidemia, and diabetes. Healthcare providers at the clinic directed many diabetic patients for diabetic management follow-up to see trends of individuals' blood levels, A1C, LDL lipids, and urinalysis for microalbuminuria. Furthermore, preventative screening with a foot exam as well as in-house referrals to optometrist and dentists were made at least annually. Yet, there were still people who are non-compliant with medication, strict nutrition regiments, or completing their blood lab exams prior to PCP follow-up.

The clinic was already providing monthly DSME classes by a registered dietitian for patients. The biggest weakness was that only one registered dietitian was involved in DSME class without BCSP. Before the DNP project, no other health professionals, such as physicians, nurse practitioners, or pharmacists, were a part of DM education. Additionally, the DSME class attendee's diabetes control and improvement were not closely monitored.

Study Population

The study was conducted in adult type II diabetes patients in the age range of 18 to 85 years old with A1C 7.0 % or above who were able to read, write, and speak English, provided informed consent, and owned a text message-capable mobile phone for the three-month study duration. Exclusion criteria included physical disabilities affecting vision or walk and being on pharmacological treatment for psychiatric disease or cancer — patients who were pregnant or had cognitive impairment that could negatively affect self-management behavior. For this pilot study, a sample of 31 participants was needed with a medium effect size, 80% power, and alpha=0.05. A total of 35 participants were needed to be recruited, considering the possibility of withdrawal from the research study.

Subject Recruitment

After IRB waive, the recruitment flyer and poster were placed in the clinic's waiting area, including eligibility requirements for the BCSP-MT program. The recruitment flyer was also be placed in each exam room so that the providers could refer to eligible patients who are interested in the study to the project team. The providers informed individuals on how to contact the project team. A patient who was self-referred or referred to the research team must initiate contact and give verbal consent to the project manager for follow-up calls. Then, the project manager contacted eligible patients via phone or in-person during the clinic visit to discuss the study and confirm eligibility. One-on-one support to enroll in the program was provided for those who are unfamiliar with texting or with lower technology proficiency.

Consent Procedure

All participants completed informed consent before they are enrolled in the study over the phone or during the clinic visit. Anticipated risk, harms, and benefits of participating in the study were discussed during the time of the consent process. Furthermore, participants were informed that they could choose to withdraw from the study anytime. Baseline and characteristic data were conducted by using the Diabetes Care Profile Section I- Demographics and Section III-Education/Advice from Michigan Diabetes Research and Training Center. Additionally, all participants completed the biometric tests, including A1C, LDL cholesterol, BMI, and BP at least two to three weeks or two months the most before beginning the BCSP-MT program. The BMI and BP were recorded in eCW by MA and A1C, and LDL cholesterol levels were electronically transcribed from the Quest Diagnostic. After baseline assessment and a face-to-face orientation, participants received a welcome text message that required a reply response as program activation (see Table 1 for Standard Protocol: Project Timeline). Patients who did not respond to the initial text message was contacted by phone before beginning the project.

Table 1 Standard Protocol: Project Timeline

STUDY PERIOD																
TIMEPOINT	Enrollment		Intervention												Evaluation	Closeout
ENROLLMENT	0-90 days prior	1-2 weeks prior	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12	Weeks 13-24	> 1 Year
Eligibility Screen																
Informed Consent																
Staff Meeting																
INTERVENTIONS																
Face-to-Face Meeting																
BCST-MT Texting																
Phone Call Coaching																
DSME Class																
ASSESSMENTS																
Baseline · The Diabetes Care Profile Section I- Demographics and Section III-Education/Advice plus Medication · The Summary of Diabetes Self-Care Activities Measure (SDSCA) · Michigan Diabetes Research and Training Center's Revised Diabetes Knowledge Test (RDKT) · Biometric data: A1C, BMI, LDL, BP																
Outcome variables · The Summary of Diabetes Self-Care Activities Measure (SDSCA) · Michigan Diabetes Research and Training Center's Revised Diabetes Knowledge Test (RDKT) · Diabetes treatment satisfaction questionnaire (DTSQ) · Biometric data: A1C, BMI, LDL, BP																
Gift cards distribution																

Risks/Harms to Participants

There were minimal anticipated risks and harms. The probability of anticipated harms and risks in the research study included possible physiological, emotional, and economic burden. Participants could have physiological harm from blood draw, such as bruising, pain, and possibly a syncopal episode. However, patients were probably aware of the minimal physiological risk from their previous experience at the time of diabetes diagnosis. A patient's episode of syncope or dizziness protocol was developed using resources from the MediaLab's online continuing education materials (MediaLab, n.d.). The clinic staff and the phlebotomist followed the protocol. If the patient felt faint before the procedure, the phlebotomist must ensure the patient's safety and instruct the patient to lie down for at least 15 minutes. The phlebotomist needed to confirm if the patient could tolerate the procedure before the blood draw. If the patient felt faint during the procedure, the phlebotomist should immediately stop the procedure by removing the needle and tourniquet, apply pressure to the puncture site, and call for assistance. The phlebotomist instructed the patient to place his head between his knees and apply a cold compress to the back of the neck. The phlebotomist should stay with the patient for at least 15 minutes to ensure a patient's recovery. If the patient felt dizzy after the blood draw, the phlebotomist should follow the same instructions as stated above. If the patient had a syncopal episode, the phlebotomist must ensure the patient's safety and call for assistance while staying with the patient. The clinic staff should inform the available provider to assess the patient.

Emotional risks may include increased pressure and stress regarding being a participant of the research study beside an individual's health status, such as diagnosed with diabetes. Participants received all the study information and had the opportunity to ask questions when they are signing the consent form. Additionally, participants received continuous support and advice regarding diabetes care management from healthcare professionals throughout the study. Patients were informed that they could choose to withdraw from the study anytime during the consent process.

Considering the clinic's population, the economic risks of the study subjects were anticipated. All patients who were diagnosed with diabetes, regardless of the study participation, were responsible for co-payment, transportation costs, healthy diet grocery shopping, medications, or other medical equipment that were required for their diabetes care. Each clinic visit and procedure were billed to uninsured participants, and insured subjects may be required a co-payment, as per usual. To improve the patient healthcare experience, the clinic provided diabetes care support for eligible patients that can minimize economic costs. Low- income, uninsured Montgomery County residents were eligible for free medical equipment such as glucometers or BP machines as well as several diabetic medications. The clinic also provided a free shuttle bus on weekdays for all patients who live in the Silver Spring area. However, uninsured non-Montgomery County residents must purchase medications and supplies out-of-pocket and could be a threat to the study, as they have low-incomes and were thus less likely to adhere to intervention and follow-up with their PCPs on a timely manner. Based on an individual's health status and disease control, patients may be required additional lab tests and follow-up visits with their PCP that involve added costs. Nevertheless, the study was intended to provide added behavior change support for participants using mobile technology adjunct to usual ongoing diabetes care. Thus, the research did not involve actual, significant additional costs to an individual with planned intervention other than text-messaging fees or no costs if using free mobile texting applications. The anticipated costs were described to participants during the consent process.

The study participants were provided with an accurate description of the risks and the anticipated benefits during the consent process. The probable benefits to be derived from the research could be gaining knowledge on diabetes self-care management and disease control with an added behavioral change support program.

Costs/Compensation for Participants

Participants were responsible for paying their lab tests and co-payment fee. However, the costs of clinic visits and blood testing were the same as usual diabetes care for study participants. Each clinic visit for

Montgomery residents paid $ 35 co-pay, and non-Montgomery residents paid $ 60 for baseline and 3-month follow-up visits. During the office visit, participant's BP and BMI were checked and documented on Electronic Medical Record (EMR) called eCW. The cost of a blood test from the in-house lab was as follows; Comprehensive Metabolic Panel $4, A1C $7, Lipid panel $6, or A1C plus Fasting blood glucose $9. The average of each Montgomery resident participant with lab tests at the baseline assessment and a 3-month follow-up visit was ranging $100- $104. The average of each non-Montgomery resident participant with lab tests at the baseline assessment and a 3-month follow-up visit was ranging from $ 150-$174. However, the anticipated costs for lab tests and co-payment for clinic visits were the same as all diabetic patients who are not participating in the study. Based on individual care, patients were responsible for purchasing glucometer, additional blood tests, or diabetes medications as ordered by his or her PCP.

Depending on the individual's text message plans and mobile carrier, participants could be charged differently. Subjects were charged ranging from $0.05 to $0.20 per text message for plans who did not have texting included in a plan. Patients with unlimited text plans typically pay $10-$20. 'TigerConnect' was a free mobile application to provide better communication between the provider and the patient. This mobile application allowed users to send free text messages securely and privately. After individuals send TigerConnect a one-time SMS containing a unique security code which cost was approximately $0.05 to $0.20 once, TigerConnect automatically verified the device and secured the phone. The application helped to upload and encrypt the data on Tigerconnect's servers using private conversation by invitation. Moreover, users could safely and securely attach files, photos, or videos to messages, and fully encrypted messages are sent through TigerConnect.

The clinic provided lunch for diabetes class attendees that were worth about a total of $100 every month. During the final face-to-face meeting, one participant was randomly selected by a ticket and received a $50 gift card after participation was completed. Participants who came to the final face-to-face meeting were given pre-paid gift cards for biometric testing (worth $16 per person).

Study Interventions

The intervention group received usual diabetes care, such as medical visits, tests, and monthly DSME classes with BCS-MT. The mobile technology support program included two weekly text messaging and monthly phone calls between the DSME class, including face-to-face sessions. Evidence-based educational materials were developed using various resources from professional organizations such as the ADA, the NIH, and the JDC. Weekly text messages included general diabetes education, recommended physical activity, dietary change, medication adherence, and preventative screening for diabetes.

1. One face-to-face session for an orientation to the BCSP-MT study was conducted at the clinic. The participants received standard information about diabetes and diabetes self-management. The SDSCA and RDKT were completed at this time. For subjects with lower technology proficiency or for those who were unfamiliar with texting received additional support during the orientation.
2. Two to three BCSP text messages were selected from educational content and were sent to participants every week for twelve weeks by the project manager. The specific topics were selected to guide participants about diet, exercise, diabetes self-management, and disease knowledge. Patients received reminders or educational information via SMS text or within the TigerConnect application. (see Table 2 for overview and Appendix F for text message examples).

Table 2. Overview of the Topics for BCSP-MT Using Text Messages

Educational Topics	**Contents for texts**
Diabetes Information	• General diabetes • Chronic complications • Medication adherence • Diabetes and alcohol or smoking • Importance of self-management
Healthy eating	• Heart-healthy diet • Tips for healthy eating • Eating out • Understanding food labels

Educational Topics	Contents for texts
Physical activity	• Recommended physical activity • Benefits of physical activity
Weight management	• Understanding the Body Mass Index • Weight loss and diabetes
Monitoring diabetes	• Understanding fasting glucose and A1C levels • Hypertension and hyperlipidemia control in diabetes care • Preventative screening
Maintaining contact with PCP	• Importance of keeping contact with your PCP • How to get prepared for your PCP visit
Emotional support and motivation	• Managing stress • Goal-setting for a healthy life

3. There were three monthly phone coaching sessions between monthly diabetes classes. This means that the participants could have contact with the healthcare team at least every two weeks: during the monthly class and phone calls. The project manager supported the study participants by addressing questions or concerns, helping them with goal-setting, and discussing diabetes care. The phone coaching session aimed to help participants learn strategies to make lifestyle changes and assisted them with emotional support with improved communication between patients and the health professional team.
4. The second face-to-face wrap-up meeting was conducted in week 13 at the clinic. The participants completed the SDSCA, RDKT, and DTSQ during the meeting. The project manager reflected on appreciation and the wonderful opportunity to participants. The project manager discussed how one participant was randomly selected for a $50 gift card and methods of delivery after evaluation.

Indicators/Outcomes to Be Measured

A three-part questionnaire was used to obtain information about the participant's characteristics such as age, sex, race, education, employment status, type of medication, and previous diabetes education. The first two

parts of questionnaires were the Diabetes Care Profile; Section I Demographics, and Section III Education/Advice from Michigan Diabetes Research and Training Center. The last part of the questionnaire was manually added with yes or no questions regarding current medications for diabetes, hypertension, or hyperlipidemia. For instance, participants were asked if their diabetes medication is taken by mouth or insulin

Table 3. Outcome Measure Tools

	Tools for outcome measures
Pre-Post	• Michigan Diabetes Research and Training Center's Revised Diabetes Knowledge Test (RDKT) • The Summary of Diabetes Self-Care Activities Measure (SDSCA) • Biometric data: BMI, BP, A1C, and LDL levels
Post only	• Diabetes treatment satisfaction questionnaire (DTSQ)

Measures were assessed at baseline and week 12. The primary outcomes were biometric measures, including A1C, BMI, BP, and LDL levels. MAs measured BMI and BP and record on eCW at baseline data collection and 3-month follow-up with their PCP. BP was measured using a calibrated sphygmomanometer after a participant has been sitting quietly for 5 minutes without eating, drinking, or smoking. The participant's feet must be flat on the floor, and his or her left arm must be straight on the table at the time of measurement. Two BP were taken, and the lowest BP will be recorded on eCW. Regarding BMI, the digital scale with a manual height rod was be used. MA measured the weight in pounds using calibrated digital scales and the height in feet and inches using the stadiometer. MA was instructed to set the scales to zero before the patient steps on the scale and asked the patient to stand with their back to the wall and to look directly forward. Patients were asked to remove heavy items from their pockets such as keys, cellphones, and wallets, and remove heavy clothing such as jackets and shoes. Subjects were advised not to eat or drink at least 3 hours before

measurement to ensure tests can be taken under the same condition. During the time of measurement, patients were asked to look straight ahead and stay still on the scales.

A1C levels provide reliable long-term glycemic control in diabetes. Phlebotomists from the in-house lab center drew blood samples for A1C and LDL levels, and results were automatically recorded in eCW. LDL cholesterol level was measured because diabetic patients tend to have lower HDL cholesterol with elevated triglyceride and LDL cholesterol levels, which increased the risk for cardiovascular disease (American Heart Association, 2016). Improvement of LDL could show that the patients adhered to self-care management and lifestyle modification. To ensure the results' accuracy, patients were advised to fast for at least 8 hours before a test, but they could drink water and take their home medication during a fast. However, participants could not drink juice, coffee, soda, and other beverages, including other activities such as chewing gum and smoking during a fast.

The secondary outcome measures were patient knowledge on diabetes self-care management using the RDKT and the SDSCA. The RDKT has a lower reading level with either a 14-item scale to evaluate general diabetes knowledge and additional a 9-item scale for the participants with insulin use. The RDKT has been widely used in many countries by diabetes researchers and educators to assess the knowledge of diabetes due to its easy access and low-cost (Fitzgerald et al., 2016). Moreover, Fitzgerald et al. (2016) combined sample analysis showed the RDKT to be a valid and reliable measure of diabetes knowledge. The study participants will be given 20 minutes to complete the RDKT at the baseline and after the three months of intervention. The SDSCA is a reliable and valid self-report questionnaire to assess an individual's self-management and the diabetes regimen such as diet, exercise, blood glucose monitoring, foot care, and smoking (Toobert et al., 2000). There was a total of 11 items about self-care activities. For items 1-10, each item was scored on a seven-point Likert scale indicating the frequency of the specified behavior in the past seven days as 0 = never and 7 = every day. The last question was a yes or no question for smoking. In addition, one item (question 6A for Medications) from the additional items for the expanded version of the SDSCA was included, and that was a

seven-point Likert scale. Therefore, the participants were asked to answer a total of 12 items. A higher sum score indicated frequent self-care management activities.

Lastly, the DTSQ was conducted at the end of the study. The DTSQ has been widely used in many countries to assess patient satisfaction with their diabetes treatment after it was internationally validated and officially approved by the World Health Organization and the International Diabetes Federation (Saisho, 2018). This questionnaire was composed of eight questions with a scale ranging from zero (very dissatisfied) to five (very satisfied). The sum of the scores of the six questions was computed, and a higher score indicated higher treatment satisfaction.

Results

General Demographics or Characteristics

The characteristics of the sample were analyzed. There was a total of 14 participants, six males, and eight females. The majority of participants were age above 60 years, which accounted for 6 participants (42.9%). Ages between 40 and 60 accounted for 5 participants (35.7%), and only 3 participants (21.4%) were aged below 40 years. Most participants had high school or GED or less education level (8 participants, 57.1%). A total of 3 participants (21.4%) had a graduate degree, 2 participants (14.3%) had a bachelor's degree, and 1 participant (7.1%) had some college level. In consideration of race and ethnicity, most participants self-identified as black or African American (8 participants, 57.1%), and 6 participants (42.9) identified as Asian. Participants were asked if they were unemployed, retired, or employed as part-time or full-time. One participant (7.1%) responded that he/she was unemployed, 6 participants (42.9%) had part-time jobs, and the other 6 participants had full-time jobs. The remaining participant responded that he/she was retired. Additionally, there were 10 participants (71.4%) who were married, 2 participants (14.3%) who were never married, and 2 participants (14.3%) who were either single, divorced, or widowed. A total of 11 participants (78.6%) did not have health insurance, but 5 participants (35.7%) among this group qualified for Mcares to receive Montgomery

County Health Financial Support for co-payment and some diabetes medication. Only three participants (21.4%) had either private, Medicaid, or Medicare.

The clinical factors of participants at baseline were analyzed. 50% of participants were on anti-hypertensive medication, and the other 50% of participants were not on an anti-hypertensive medication regimen. Among 14 participants, 6 participants (42.9%) were on medications for high cholesterol, and the remaining 8 participants were not on treatment. There were 3 participants with normal BMIs, 5 participants with overweight BMIs, and 6 participants who were obese. The mean BMI was 29.4 (SD 4.94), ranging from 23.95 to 39.32. The mean HbA1C of participants at baseline was 8.9 (SD 1.50), ranging from 7.1 to 12.3. Based on the descriptive statistics, both male and female participants who were Black or African American and were in the 40s- 60s regardless of marital status tend to have higher A1C compared to other participants. The mean pre-intervention LDL level was 91.4 (SD 22.36), ranging 50-139. Each participant's pre-implementation blood pressure was separately analyzed in systolic and diastolic. The mean systolic BP of all participants at baseline was 121.3, and diastolic BP was 72.4. A total of 11 participants responded that they check FBG and the mean days of FBG checked in a week was 2.4 days. Among 14 participants, 12 participants (85.7%) were taking oral DM medication, while 2 participants (14.3%) were taking both oral and insulin. Regarding previous diabetes education, 8 participants (57.1%) responded that they never had previous diabetes education, unlike 6 participants (42.9%) who had participated in diabetes education.

Table 4. The Characteristics/Demographics of the Samples at Baseline & Post-intervention

	Total sample= before intervention N=n N=14	**Post-intervention who completed ONLY biometrics** n=11	**Post- who completed BOTH biometrics and questionnaires** n=7	**Statistics**
Gender				X^2
Male	6 (42.9%)	4 (36.4%)	2 (28.6%)	
Female	8 (57.1%)	7 (63.6%)	5 (71.4%)	
Age				X^2
<40	3 (21.4%)	3(27.3%)	2 (28.6%)	
40-60	5 (35.7%)	3 (27.3%)	2 (28.6%)	
>60	6 (42.9%)	5 (45.5%)	3 (42.9%)	

Race/Ethnicity				X2
White	0 (0.0%)	0 (0.0%)	0 (0%)	
Black or African American	8 (57.1%)	5 (45.5%)	2 (28.6%)	
Asian or pacific islander	6 (42.9%)	6 (54.5%)	5 (71.4%)	
Hispanic	0 (0.0%)	0 (0%)	0 (0%)	
Marital Status				X^2
Never married	2 (14.3%)	1 (9.1%)	0 (0%)	
Married	10 (71.4%)	9 (81.8%)	7 (100%)	
Single/Divorced/Widowed	2 (14.3%)	1 (9.1%)	0 (0%)	
Health insurance				X^2
Yes	3 (21.4%)	1 (9.1%)	1 (14.3%)	
No	6 (42.9%)	5 (45.5%)	3 (42.9%)	
MCares	5 (35.7%)	5 (45.5%)	3 (42.9%)	
No answer	0 (0%)	0 (0%)	0 (0%)	
Do you check FBG?				X^2
YES	11 (78.6%)	7 (63.6%)	7 (100%)	
NO	3 (21.4%)	0 (0%)	0 (0%)	
No answer	0 (0%)	4 (36.4%)	0 (0%)	
How many days a week do you check FBG?	2.4 (SD = 2.34), range: 0-7	2.6 (SD=2.50), range: 0-7	3.14 (SD=2.12), range 1-7	Paired t-test
Received diabetes education? Pre- data only				X^2
YES	6 (42.9%)	6 (54.5%)	3 (42.9%)	
NO	8 (57.1%)	5 (45.5%)	4 (57.1%)	
Type of DM medication				X2
Not taking meds	0 (0%)	1 (9.1%)	1 (14.3%)	
Oral	12 (85.7%)	10 (90.9%)	6 (85.7%)	
Insulin	0 (0.0%)	0 (0%)	0 (0%)	
Both	2 (14.3%)	0 (0%)	0 (0%)	

The mean pre-diabetes knowledge RDKT was 26.2, ranging from 0 to 14 of a total score of 23. A total of 5 (35.7%) out of 14 participants did not answer the questionnaire, 3 participants (21.4%) had a score of 5, 2 participants (14.3) had a score of 9, 2 participants (14.3%) had a score of 10, and remaining 2 participants (14.3%) had a score of 14. Based on the descriptive statistics, in both black or African American males and females who were aged below 40 and between 40 to 60, regardless of marital status had higher scores on the diabetes knowledge RDKT test.

Each category of self-care activities was analyzed to learn changes in self-care activities from pre-test to post-test in detail. A high self-care activity score indicates that a patient actively participates in his diabetes self-care activities. The mean of the pre-self-care activities score was 26.21 at SD 14.07, ranging from 12 to 60.

Both males and females aged between 60 to 85 years old who were either black/African American and Asian or pacific islander had higher scores on the pre-self-care activities questionnaire regardless of marital status. Most patients rated that they participated in diet management (mean =9.5), blood sugar testing (mean= 5.93), and medication adherence (mean =5.50). Many patients tended not to check their foot care (mean=1.29). There was only one participant who smoked cigarettes (7.1%) and stated that he/she smoked five cigarettes per day.

Study findings

The clinical factors of participants after the intervention were analyzed in two groups. For instance, only 7 participants actively participated in project activities like attending diabetes classes, answering phone-coaching, and face-to-face meetings. They also completed both biometrics and questionnaires for post-intervention outcome measures. The other four participants (a total of 11 participants, including the previously mentioned seven participants who did both) completed only biometrics after post-intervention. Even though the remaining three participants sometimes answered the phone calls and attended the diabetes classes, they have not completed both post-intervention outcome measures. They also have not followed up with their PCP for more than three to four months during the project.

Primary outcomes

The characteristics of the seven participants who completed the DNP project showed that Asian or pacific islander (5 people, 71.4%), females (#5, 71.4%), people in the age range of 65 to 85 years old (3, 42.95%), and High school or GED or less education levels (4, 57.1%) actively participated in the program from the beginning to end. All seven participants were married (7, 100%) and check their FBG (7, 100%) with a mean of 3.14 times a week ranging 1-7 times a week. Six participants among this group did not have health insurance, but three of them were qualified to receive financial support from Montgomery County (Mcares). In consideration of their biometric outcome measures, the mean post-A1C was 8.47 ranging from 6.6 to 10, and the mean post-LDL level was 92.0 ranging from 56 to 144. The mean post-systolic BP was 126.57 (ranging 98-

148), while the mean post-diastolic BP was 73.14 (ranging 54-84). The majority of this group was overweight (4, 57.1%) with a mean BMI of 28.35. To analyze statistical findings, paired t-tests were used for A1C, BP, BMI, and LDL in this group. Paired differences were as follows; the mean post-BMI was reduced by 0.02, and post-LDL was reduced by 5.14 compared to the baseline. At the same time, there was a rise in the mean of post-A1C by 0.14 and the mean of post-systolic by 3.14 from the baseline. The mean of post-diastolic remained the same. Table 3 a-3 shows a variable table for pre- and post- biometrics for those 7 participants who completed both post outcome measures with statistics and P values. Most patients reported that they were not on antihypertensive medication (4, 57.1%), but they were more likely on medication for high cholesterol (4, 57.1%). The majority of this group was taking oral diabetes medication (6, 85.7%), but one participant stopped taking oral blood glucose-lowering medication without medical advice. Two of the patients were eligible for Mcares, and their post-A1C was increased from the baseline. They used to receive diabetes medication from the clinic pharmacy for free but reported that they were not able to fill the diabetes medication for about two months due to a lack of supplies. Pre and post biometrics for 11 people who completed only biometrics (including the previously mentioned 7 participants) showed that there were reductions in the post- BMI, A1C, LDL, and diastolic BP by the mean of 29.84 (-0.08), 8.43 (-0.19), 91 (-4.45), and 72.36 (-1.27) respectively. The mean of post-systolic was increased to 122.6 (+1.27).

Table 5. Pre and Post Biometrics for People Who Completed ONLY Biometrics

	Intervention group		Statistics and P values
	Pre n=11	Post n=11	
BMI	29.93 (SD = 5.27)	29.84 (SD=5.01)	0.733
Systolic BP	121.27 (SD = 16.52)	122.6 (SD=15.05)	0.787
Diastolic BP	73.64 (SD = 10.11)	72.36 (SD=10.15)	0.463
LDL	95.45 (SD = 22.96)	91 (SD=26.49)	0.524
A1C	8.6 (SD = 1.19)	8.43 (SD=1.30)	0.632

Table 6. Pre and Post Biometrics for People Who Completed BOTH Biometrics and Questionnaires

	Mean (SD)		P value
	Pre n=7	Post n=7	
BMI	28.37 (SD = 5.36)	28.35 (SD=5.10)	.959
Systolic BP	123.43 (SD = 13.94)	126.57 (SD=17.46)	.590
Diastolic BP	73.14 (SD = 9.78)	73.14 (SD=9.72)	1.0
LDL	97.14 (SD = 28.25)	92 (SD=28.61)	.626
A1C	8.33 (SD = 1.04)	8.47 (SD=1.29)	.808

Secondary outcomes

The mean of pre-diabetes knowledge RDKT of the 7 participants who completed the BCSP-MT was 5.43 ranging from 0 to 14 of a total score of 23. This was slightly lower than the mean of all 14 participants, which was 5.79. After completion of the project, there was a 120.99% improvement in diabetes knowledge RDKT in the 7 participants as the post-test mean was 12.0 ranging from 2 to 18 with p=0.041. The smallest improvement of the diabetes knowledge RDKT after the intervention was a score of 2 with a pre-test score of 0 in an Asian or pacific islander female, age between 60 - 85 years. The most considerable improvement of the post-RDKT score was 17, with a pre-test score of 0 in a black or African American female aged between 40 to 60 years. Another Asian or pacific islander female aged between 40 to 60 years had the highest score of the post-RDKT of 18 with a pre-test score of 5. There were only two males among the 7 participants. An Asian or pacific islander male who was aged between 60 to 85 years had good improvement in the post-RDKT score (post- a score of 10 & pre- 0) while the post-RDKT score of the other Asian or pacific islander male who was younger than 40 years remained the same as the pre-test score of 9.

The higher the self-care activities score (SDSCA) indicates that a patient actively participates in their diabetes self-care activities. The mean of pre-self-care activities score of the 7 participants who completed both biometrics and questionnaires was 28.0 (SD=18.91) ranging from 12 to 60, which was slightly higher than all

14 participants, 26.21 at SD 14.07. After completion of the BCSP-MT, there was a 29.61% improvement in the mean of the post-self-care activities score of the 7 participants, as the mean was 36.29 ranging from 24 to 57 with p=0.19. Among the 7 participants, the lowest post- SDSCA score was 24, and the person who had this score was an Asian or pacific islander female who was aged between 40 to 60 years old. Her pre-test score was 17. The highest post- SDSCA score of 57 was achieved by an Asian or pacific islander female who was older than 60 years old. However, her post-test SDSCA score was reduced from the pre-test (a score of 60) by 3. Females with bachelor's degree achieved the greatest improvement of the post-SDSCA score. A Black or African American female who was aged 40 to 60 years had the difference pre- and post-test SDSCA score of 33 (pre- 15, post- 48). Another female was an Asian or pacific islander who was older than 60 years old with the difference score between pre- and post-test of 20 (pre-12, post-32). Unexpectantly, there were three participants with a reduction of the SDSCA score by 3 to 10 from their pre-test score (ID#10: pre-60, post-57, ID#11: pre-36, post-26, ID#14: pre-44, post-41). One of those three participants was the one who stopped taking diabetes medication without medical advice.

Table 7. Pre and Post Questionnaires for People Who Completed BOTH Biometrics and Questionnaires

	Intervention group		Paired t-test P values
	Pre n=7	Post n=7	
Diabetes knowledge total	5.43 (SD= 5.71)	12 (SD=5.63)	0.041
Diabetes self-care activities total	28.0 (SD= 18.91)	36.29 (SD=12.71)	0.19

Each category of self-care activities was analyzed to learn changes in self-care activities from pre-test to post-test in detail. In the pre-test, the seven participants who completed the project had more likely participated in self-care activities. For this reason, the 7 participants had better mean days of self-care activities in a week for all the categories compared to the mean days of all 14 participants which also included the seven people; exercise (mean=5.57 vs. 4), blood sugar testing (mean= 6.71 vs. 5.4), medication adherence (mean =5.6 vs. 5.5), foot care (mean= 1.57 vs. 1.29), and smoking status (none vs. 1). After completion of the project, there was

considerable improvement in many categories of self-care activities among those 7. The post-intervention mean days of self-care activities in diet management was 14.3 (compared to pre-intervention of 8.57, p=0.007), exercise was 7.43 (pre- 5.57, p= 0.40), and foot care was 3.57 (pre-1.57, p=0.105). However, both the mean self-care activities of days a week in blood-glucose monitoring and medication adherence were reduced after the intervention. For example, the 7 participants' mean days of a week for blood-glucose monitoring after the intervention was 4.14 compared to 6.71 from the baseline (p=0.26). The medication adherence after the intervention was 4.9, while the pre-intervention was 5.57 (p=0.557).

Table 8. The Mean Scores of Pre and Post-Self-care Activities

	Intervention group		
	Pre n=7	Post n=7	Test and p values
Diet	Mean 8.57 of days a week	Mean 14.3 of days a week	Paired t-test .007
Exercise	Mean 5.57 of days	Mean 7.43 of days	Paired t-test .403
Blood-glucose testing	Mean 6.71 of days	Mean 4.14 of days	Paired t-test .260
Foot care	Mean 1.57 of days	Mean 3.57 of days	Paired t-test .105
Smoking status	0 participant	0	McNeimar's test
Number of cigarettes per day			Paired t-test
Medication	Mean 5.57 of days	Mean 4.9 of days	Paired t-test .557

The rate of monthly diabetes class attendance and the number of people who answered the phone for monthly coaching were analyzed. The initial face-to-face meeting was placed on the same day as the September diabetes class. A total of 8 study participants (57.1%) attended for diabetes class while there was a total of 11

monthly diabetes class attendees regardless of BCSP-MT program participation. Among the 7 participants who completed the BCSP-MT from the beginning to the end, 4 participants (57.1%) attended the September diabetes class. In October, patients were reminded of the diabetes class via phone calls and text messages, but only 1 BCSP-MT participant (7.1%) attended the class out of a total of 8 diabetes class attendees. None of the 7 participants who completed the project participated in the class. In November, there were 3 BCSP-MT participants (21.4%) out of 14 who attended the diabetes class while there was a total of 13 diabetes class attendees. Two (28.6%) out of 3 BCSP-MT participants who attended the November diabetes class were of 7 people who completed the BCSP-MT. Between September to November, black or African American males who were aged between 60 to 85 years were more likely to participate in monthly diabetes classes.

The first phone coaching was conducted on October 8, 2019. A total of 8 participants (57.1%) answered the call, and the voice messages were recorded for the remaining 6 participants (42.9%), who set the voice message features. During the first phone coaching, three (42.9%) out of 8 participants were from the 7 participants. For the second phone coaching, each of 14 participants was asked a convenient time and day to talk over the phone via text messages. The second phone coaching was conducted on October 30, 2019. A total of 12 participants (85.7%), which included all the 7 participants (100%) answered the phone and discussed issues and concerns regarding self-care activities. The last phone call coaching was delivered on December 04, 2019, for questions and answers regarding diabetes self-care activities, preventative screenings, and face-to-face meetings. A total of 9 participants (64.3%) answered the phone for the last phone coaching in December 2019. All the 7 participants who completed both biometrics and questionnaires answered the phone (100%). Unlike monthly diabetes class participation, females who were both Black/African American and Asian or Pacific Islanders were more likely to answer phone calls throughout all age groups.

Table 9. The Frequency of Phone Calls and DSME Attendance

Variable	Frequency (%)
Phone call Answered	
1st call	8 (57.1%)
2nd call	12 (85.7%)

3rd call	9 (64.3%)
DSME Attendance	
1st class	8 (57.1%)
2nd class	1 (7.1%)
3rd class	3 (21.4%)
Retinal Exam	
Yes	10 (71.45%)
No	4 (28.6%)

Participant satisfaction and acceptability

During the final face-to-face meeting on January 11, 2020, a total of 7 participants (50%) joined the meeting and completed both biometrics measurements and post-intervention RDKT and the SDSCA questionnaires, including the diabetes program satisfaction survey. For the satisfaction of the BCSP-MT, descriptive statistics were used at the end of the program. This questionnaire had a total of 8 questions, which consisted of one yes or no question and seven questions with a five-point Likert scale. A higher sum score (the highest = 35) indicated better satisfaction with the BCSP-MT. One yes or no question was 'would you recommend this form of treatment to someone else with your kind of diabetes?' The seven participants who completed the BCSP-MT were considerably satisfied with the BCSP-MT with the mean of 32.29 treatment satisfaction rates ranging from 24 to 35. Additionally, all 7 participants were willing to recommend BCSP-MT to others (100%).

Table 10. Post Diabetes Program Satisfaction

	Intervention group n=7	Statistics and P values
Post Satisfaction Total	32.29 (SD=3.99)	Mean (SD)
Q7. Recommend to others		Mean (%, SD)
	YES	NO
	7 (100%, SD= 0.00)	0 (0%)

Discussion

Literature results and the overall summary of findings

Comprehensive diabetes care has been launched to promote behavior changes involving self-care and a healthy lifestyle, and to improve health outcomes. Self-management education is designed to help diabetic patients gain knowledge and skills to achieve proper diabetes self-care. However, recent research showed that education alone is ineffective and insufficient in promoting sustainable behavior change (Hood et al., 2015). In recent years, mobile phone technologies have emerged as a promising method for behavioral changes towards long-lasting healthier lifestyles.

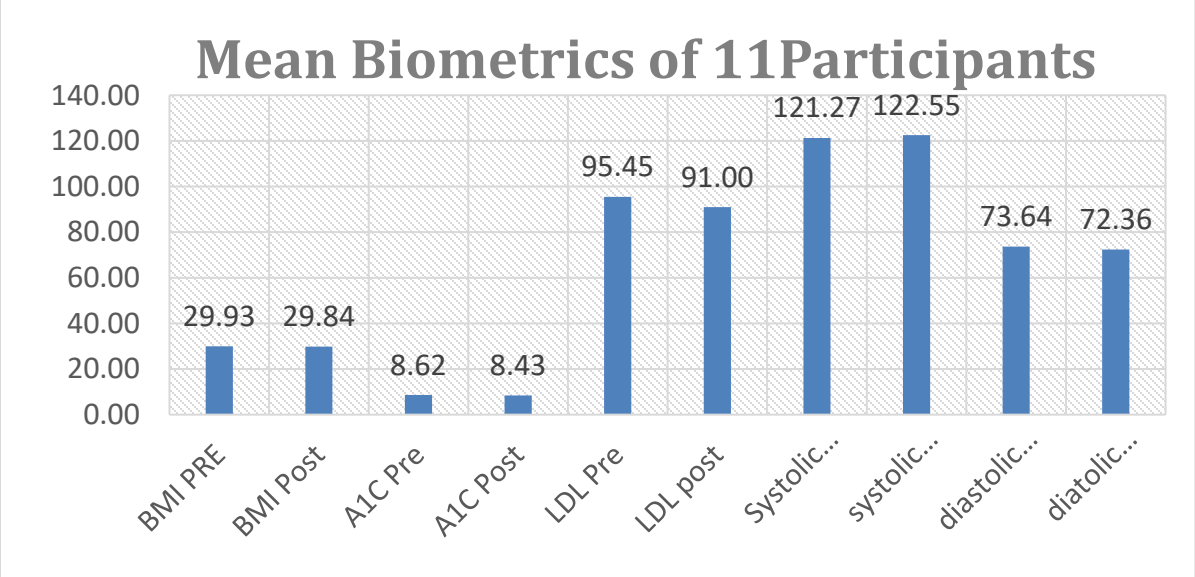
An ongoing self-directed behavior change support model encourages individuals to gain insight into self-care barriers and make sustainable behavioral changes through ongoing communication with the medical team. Ultimately, patients with diabetes can improve their ability to manage their diesase (Funnell, Tang, & Anderson, 2007). Literature review findings supported the implementation of BCSP-MT with greater improvement in A1C, weight, lipid profile, physical activity, and diabetes self-care behaviors (Agboola et al., 2016; Andrews et al., 2011; Capozza et al., 2015; Griffin et al., 2014; Nundy et al., 2014; Lari, Noroozi, & Tahmasebi, 2018).

This DNP project aimed to assist type 2 diabetes patients in order to improve clinical outcomes, disease knowledge, and positive self-care practices through patient-centered, evidence-based DSME with added BCSP-MT within a primary care setting. Evaluation of the data revealed encouraging results in regards to program implementation. This DNP project found that DSME paired with BCSP-MT led to statistically significant improvements in diabetes knowledge ($p=0.041$) and modest improvements in self-care activities ($p=0.19$), including glucose monitoring, maintaining a healthier diet, foot care, and exercise.

The effects of the intervention were also seen in biometric data with a reduction in BMI, LDL, and diastolic BP. Any reduction in A1C will likely decrease the risk of significant micro- and macrovascular

diabetic complications. Although 7 participants who completed the entire project had a slight increase in A1C (pre- 8.33, post- 8.47), there was a small reduction in A1C (pre- 8.61, post- 8.43) in 11 participants, who completed only biometrics. The average decrease of 0.18% (p=0.632) was seen in this study, but it did not reach the level chosen to signify clinical significance of p=0.05 or have the expected outcome of A1C below 7%. Therefore, this study is unable to conclude that the effects of the DSME paired with BCSP-MT in biometric measures were clinically significant. However, the project showed a high level of acceptability with the majority of participants finding that the program was useful and were willing to recommend to others. Participants preferred BCSP-MT compared to voluntary DSME attendance due to time constraints.

Figure 1. Pre and Post Biometrics Change in 11 participants



The implication for Healthcare Policy

Social determinants of health (SDOH) are directly related to the distribution of resources and affect an individual's health behaviors. The five categories of the Healthy People 2020 SDOH Framework include social and community context, education, economic stability, neighborhood and built environment, and health and health care (HealthyPeople.gov, n.d.). Researchers have stressed the importance of recognizing SDOH in diabetic patients along with individual factors. In the literature review of SDOH for patients with diabetes, there

was a disproportionate burden of type 2 diabetes in the immigrant population, especially African Americans and Hispanics or Latinos, due to many environmental factors, economic instability, a lack of access to medical care, or culture and community support (Clark & Utz, 2014). Findings showed that patients had high rates of poverty with 60% living below the poverty line. Additionally, they had low education attainment with 80% not entering college and among those people, 33% did not complete elementary school. This population also lacked access to both healthcare and healthy food.

Similar to Clark & Utz's (2014) findings, a majority participant population of this DNP project was identified as low-income, uninsured, minority immigrants. During the SWOT analysis, the biggest obstacle for this DNP project was identified as an individual's financial status, including eligibility for free medication and co-payment for uninsured Montgomery County residents. Many participants could not fill their medications or follow-ups with their PCP due to the County's eligibility changes, as well as organizational structure changes, such as an increased co-payment for each visit. These changes negatively impacted their adherence to the intervention and their diabetes control and led to withdrawal from the study. Many participants preferred BCSP-MT than attending DSME classes because of easy access, continuous communication, and no time constraints as well as no costs.

Healthcare policymakers should continuously evaluate disparities and develop approaches to reduce health disparities through CDC programs that address SDOH such as "Built Environment and Health Initiative," "National Program to Eliminate Diabetes-Related Disparities in Vulnerable Populations," and "Partnerships to Improve Community Health" (CDC, 2016). These initiatives are designed to improve the health of communities and reduce the prevalence of this chronic disease by building multisector partnerships with community-based organizations and public health offices (CDC, 2016). Policies and programs should reduce health disparities so people can have equal access to affordable, individualized, high-quality healthcare.

Implications for Practice

The findings from this study suggest that primary care clinics should make changes to improve diabetes care management using DSME paired with BCSP-MT. The clinic noticed several issues regarding diabetes management and the importance of making plans to increase the number of completed HbA1C tests for diabetic patients. While performance measures-based diabetes management is one good predictor of patient outcomes and risk prevention, healthcare providers must develop patient-centered diabetic management plans for a higher quality of care and better patient outcomes (Mitri & Gabbay, 2016). In support, Inzucchi et al. (2012) stressed the importance of individualized patient care based on health determinants and disparities such as patient behavior, comorbidities, cultural differences, language barriers, and socioeconomic status.

Clark & Utz (2014) found that social support or networks had positive influences on diabetes self-care management and health maintenance if patients receive culturally-appropriate education within healthcare clinic settings. Furthermore, patients had an increased quality of life and better glycemic control when they had positive patient and healthcare team communication. They also preferred when diabetes care teams included nurses as communicators. The DNP project provided disease-related education, self-care management, and continuous support through ongoing communication. Thus, patients could have sustainable and healthier lifestyles through adherence to pharmacological therapy, self-care management, and physician practice patterns for diabetes control management. The participants had improvement in diabetes control, self-care management, and knowledge with high acceptability of and satisfaction with BCSP-MT. The BCSP-MT can provide diabetes self-management support at a low cost for individuals through continuous communication between the patient and the healthcare team.

The main goal of individual behaviors or self-managed care is to achieve better diabetic control and health-related quality of life. This BCSP-MT project can help an individual can have sustainable behavior changes toward a better and healthier lifestyle such as diet, exercise, compliance with medications, preventative screenings, and PCP follow-ups. Therefore, primary care clinics should consider implementing BCSP-MT,

partnering with community resources, and staying informed on local, state, and national policies affecting the SDOH (AAFP, n.d.).

Plans for sustainability and future scholarship

The limitation of this study was its small sample size and a high level of loss to follow-up for post-questionnaires. The biggest challenge was the difficulty with recruitment due to the clinic's unique patient population, which resulted in a small sample size. Many patients were referred to the program by their PCP or self-referred, but many patients did not meet the inclusion criteria. Another reason for the low recruitment was that the intervention was delivered in English, where the clinic has high rates of diabetes in ethnic minorities with limited English proficiency. More importantly, marital status, ethnicity, age groups, and education levels had a significant effect on the completion of the program. Therefore, further research needs to consider demographic factors and asses the effectiveness of BCSP-MT in multiple languages that would impact the quality of improvement in diabetes care.

Moreover, the project was conducted on one group without a controlled group for comparison of the effectiveness of BCSP-MT interventions. Due to time restrictions, the DNP project was conducted for a short term, though longer-term was preferred. Additionally, the project was carried in the end-of-year season between September to December. Participants verbalized that it was challenging for them to have strict self-care management and lifestyle during this time because of family gatherings for holidays. The DNP project had some improvement in biometric measures, but these improvements are expected to be greater if BCSP-MT is delivered for a longer period of time, preferably throughout a year. The future studies on quality improvement for diabetes self-care management should consider six or more months of study with a comparison of outcomes between control and intervention groups at pre-, 3-month, and 6-month or more intervals to find sustained change.

Conclusion

This DNP project explored the effectiveness of mobile technology in diabetes self-management that has previously been shown to improve diabetes outcomes. Findings indicated that a behavior change support program using mobile phones in a primary care setting improved biometric data, diabetes knowledge, and self-care activities. Significant diabetes complications can be minimized when healthcare workers provide evidence-based education and ongoing supports to improve patient's clinical outcomes by sustaining healthier self-care activities. Participants reported that they were very satisfied with the program and ongoing support from the medical team. Marital status, ethnicity, age groups, and education levels had a significant effect on the completion of the program. Demographic factors should be considered when planning future practice for quality improvement in diabetes care. The limitation of the project includes the small convenience of the study group without a control group for comparison. Further research on a larger sample with a randomized control and 3- and 6-months intervals would increase the cogency of the study. The project shows the BCSP-MT can provide diabetes self-management support at a low cost and increase a sense of receiving continuity of care. This project also showed that a behavior changes support program using mobile phones has the potential for improving diabetes self-care activities and outcomes. Thus, current practice should explore this program further.

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Appendix 7: Table of Evidence

Article #	Author & Date	Evidence Type	Sample, Sample Size, Setting	Study findings that help answer the EBP Question	Observable Measures	Limitations	Evidence Level & Quality
#1	Agboola, S., Jethwani, K., Lopez, L., Searl, M., O'Keefe, S., & Kvedar, J. (2016).	a 2-arm randomized controlled trial 6months	N=126 (intervention: n=64; control: n=62) English- or Spanish-speaking patients with glycated hemoglobin A1c (HbA1c) >7. The control group received a pedometer too without personalized messages The intervention group received a pedometer, interactive	At 6 months, the intervention group had significantly higher monthly step counts in the third (risk ratio [RR] 4.89, 95% CI 1.20 to 19.92, P=.03) and fourth (RR 6.88, 95% CI 1.21 to 39.00, P=.03) months of the study compared to the control group. However, over the 6-month follow-up period, monthly step counts did not differ statistically by group (intervention group: 9092 steps; control group: 3722 steps; RR 2.44, 95% CI 0.68 to 8.74, P=.17).	Physical activity measured by a pedometer. PA stage of behavior change via the physical activity stage of change questionnaire HbA1c, weight, and participant engagement. The patient's perception of usability and	The requirement of a computer with Internet access to upload activity data coupled with problems installing the pedometer software introduced a number of operational challenges that increased the attrition rate in this study - approximately 24%. Did not evaluate the effectiveness of the different types/themes of messages. As a result, researchers	Level I High quality

			personalized messages twice a day and standard diabetes care 4 health care centers affiliated with Massachusetts General Hospital 6 months	HbA1c decreased by 0.07% (95% CI –0.47 to 0.34, P=.75) in the TTM group compared to the control group. Within groups, HbA1cdecreased significantly from baseline in the TTM group by –0.43% (95% CI –0.75 to –0.12, P=.01), but nonsignificantly in the control group by –0.21% (95% CI –0.49 to 0.06, P=.13). On a scale of 1 to 10, the overall mean participant rating of the usefulness of TTM was 8.62 (SD 1.79, range 4-10). A great majority of participants (94%, 43/46) would recommend TTM to their friends, 72% (33/46) reported that they would like to	satisfaction with the text	are not able to tell from this study which of the daily feedback, reminders, or educational-motivational messages was directly responsible for study effects. Due to the self-report nature of the stage of change questionnaire, participants may have overestimated their stage of change at baseline	

				keep using the program, and 78% (36/46) would buy it for themselves or for another if it were for sale.			
#2	Andrews, R., Cooper, A., Montgomery, A., Norcross, A., Peters, T., Sharp, D., … Dayan, C. (2011).	Multicentre, parallel-group, randomized-computer generated allocation, controlled trial 12 months	Adults aged 30–80 years with newly diagnosed type 2 diabetes N=593 Control = 99 Diet regimen with monthly nurse support = 248 latter plus a pedometer-based activity programme= 246 Usual care (initial dietary consultation	At 6 months, glycaemic control had worsened in the control group (mean baseline HbA1c percentage 6·72, SD 1·02, and at 6 months 6·86, 1·02) but improved in the diet group (baseline-adjusted difference in percentage of HbA1c –0·28%, 95% CI –0·46 to –0·10; p=0·005) and diet plus activity group (–0·33%, –0·51 to –0·14; p Improvements were also seen in bodyweight and	Glycated haemoglobin A1c (HbA1c) concentration, blood pressure, BMI, lipid profile, insulin resistance at 6 &12 months	Several reasons might explain why no additional benefit was achieved with use of an activity program:. Activity undertaken might have been of insufficient intensity or been the incorrect type. The timing of intervention could have been too early in the disease process to show additional response.	Level I High quality

			and follow-up every 6 months; control group), An intensive diet intervention (dietary consultation every 3 months with monthly nurse support) The latter plus a pedometer-based activity programme, in a 2:5:5 ratio. 217 general practices in southwest England 12 months	insulin resistance between the intervention and control groups. Blood pressure was similar in all groups. Improvements were also seen in both study intervention groups at 6 months in concentrations of HDL cholesterol and triglycerides, more so in the intensive diet and activity group than in the intensive diet alone group, although values were similar at 12 months		The modification of two behaviors simultaneously diluted the effect of both.	

#3	Capozza, K., Woolsey, S., Georgsson, M., Black, J., Bello, N., Lence, C., … North, C. (2015).	Randomized, controlled trial with two arms	93 poorly controlled type 2 diabetes with A1C >8%. Usual care = 35 VS usual care with texting = 58 19 Primary care clinics in the Salt Lake Metropolitan Statistical Area 6 months	At 90- 180 days, there were no statistically significant differences between the intervention and control groups in terms of change in A1C (P> 0.05). However, both groups showed improvement. 29% of program users demonstrated frequent engagement (texting responses at least three times per week) for a period of ≥90 days. Questionnaire- Patients reported high satisfaction with the program, with individual questions all scoring above 3 (on a 4-point scale), and a mean	A1C data from EHR from baseline to 90 and 180 days. An exit questionnaire, the 8-question Client Satisfaction Questionnaire (CSQ-8) of the program using the four-point scale	Power issues for the analysis- the study targeted patients with poorly controlled diabetes who were likely more difficult to recall to the clinic for regular A1C testing. Change in A1C, is difficult to affect in a short timeframe (6 months), and the sample size was small	Level I Good quality

				total satisfaction score of 27.7 out of 32.			
#4	Dobson, R., Carter, K., Cutfield, R., Hulme, A., Hulme, R., McNamara, C., Maddison, R., Murphy, R., Shepherd, M., Strydom, J., … Whittaker, R. (2015).	A 3-month, nonrandomized pilot study Mixed method design including quantitative measure and phone interview	Adults (aged 17 to 69 years) with type 1 (n=12) or type 2 diabetes (n=30), a HbA1c over 70 mmol/mol (8.6%), and who owned a mobile phone (n=42) were recruited to take part in a 3-month pilot study of Self-Management Support Program 4 Blood Glucose (SMS4BG) Primary care setting 3 months	HbA1c results indicated a positive impact of the program on glycemic control with a significant decrease in HbA1c from baseline to follow-up. 93% of participants with all reporting SMS4BG to be useful and appropriate to their age and culture. Reported a range of perceived positive impacts of SMS4BG on their diabetes and health behaviors.	HbA1c Patient satisfaction and perceptions of the usability of the program by phone interviews	The absence of a control group and a small sample size. The lack of complete follow-up HbA1c results limits the generalizability of the improved glycemic control results.	Level II Low quality

#5	Dobson, R., Whittaker, R., Jiang, Y., Maddison, R., Shepherd, M., Mcnamara, C., … Murphy, R. (2018).	Nine month, two arm, parallel randomized controlled trial	N= 366 participants aged 16 years and over with poorly controlled type 1 or type 2 diabetes (HbA1c ≥65 mmol/mol or 8%) n=183 intervention group with text message support n=183 control Primary and secondary healthcare services in New Zealand.	The reduction in HbA1c at nine months was significantly greater in the intervention group (mean −8.85 mmol/mol (standard deviation 14.84)) than in the control group (−3.96 mmol/mol (17.02); adjusted mean difference −4.23 (95% confidence interval −7.30 to −1.15), P=0.007). Of 21 secondary outcomes, only four showed statistically significant improvements in favor of the intervention group at nine months. Significant improvements were seen for foot care behavior (adjusted mean difference 0.85 (95% confidence	Change in HbA1c from baseline to nine months. Secondary outcomes included change in HbA1c at three and six months, and self-efficacy, diabetes self care behaviors, diabetes distress, perceptions and beliefs about diabetes, health related quality of life, perceived support for diabetes management, and intervention	The difficulty with recruitment. One reason for the low recruitment was the required time needed by clinicians to identify and refer patients to the study, which was not always available. Longer term follow-up of participants was not feasible within the current study. Secondary outcome assessors were not blinded to treatment allocation, which could have introduced bias in follow-up data	Level I High quality

				interval 0.40 to 1.29), P<0.001), overall diabetes support (0.26 (0.03 to 0.50), P=0.03), health status on the EQ-5D visual analogue scale (4.38 (0.44 to 8.33), P=0.03), and perceptions of illness identity (−0.54 (−1.04 to −0.03), P=0.04). High levels of satisfaction with SMS4BG were found, with 161 (95%) of 169 participants reporting it to be useful, and 164 (97%) willing to recommend the programme to other people with diabetes.	engagement and satisfaction at nine months	collection of secondary variables.	
#6	Griffin, S., Simmons, R., Prevost, A.,	Randomized controlled trial	N=478	There were no significant differences between groups in	Primary outcomes included	Objective measures of physical activity,	Level I High quality

	Williams, K., Hardeman, W., Sutton, S., … Kinmonth, A. (2014).		Control group, intensive care only n= 239. Intervention group (intensive care plus a theory-based behavior change) n=239 34 general practice, primary care setting, in Eastern England Age 40 to 69 years with recently diagnosed screen or clinically detected diabetes.	physical activity (difference: +1.50 kJ kg −1 day−1; 95% CI −1.74, 4.74), plasma vitamin C (difference: −3.84 μmol/l; 95% CI −8.07, 0.38), smoking (OR 1.37; 95% CI 0.77, 2.43) and plasma drug levels (difference in metformin levels: −119.5 μmol/l; 95% CI −335.0, 95.9). Participants in the intervention group reported significantly higher levels of SF-36 physical functioning, SF-36 change in health, health utility (EQ-5D) and satisfaction with diabetes services than those in the comparison group.	physical activity energy expenditure (individually calibrated heart rate monitoring and movement sensing), change in objectively measured fruit and vegetable intake (plasma vitamin C), medication adherence (plasma drug levels) and smoking status (plasma cotinine levels) at 1 year.	smoking and medication adherence at baseline would have improved precision and enabled researchers to assess change over time. However, such detailed measurement might increase the salience and influence the behavior of participants in both groups	

				Cardiovascular risk factors and self-reported behavior improved in both groups with no significant differences between groups			
#7	Lari, H., Noroozi, A., & Tahmasebi, R. (2018).	Quasi-experimental study. Pre-post test	A short message service (SMS) group =37 type II diabetes patients control group= 36 type II diabetes patients 3 months	As compared with the control group, changes in mean scores of perceived self-efficacy (P = 0.001) and family support (P = 0.046) of physical activity in the training group were significantly greater and perceived barriers (P < 0.001) were significantly lower over time. SMS reduced the participants' perceptions of barriers to undertaking physical activity. also, sending	SMS based on a health promotion model (HPM) on the physical activity of diabetic patients Three-part questionnaire. The first part contained information about the participant's characteristics (e.g., age, sex, education, household	As several factors, including age, social class, education level, and economic status, influence people's perceptions of health, it should be expected that training interventions aimed at changing behavior do not have much impact on health status.	Level II High/good quality

				training messages through SMS to the families of diabetic patients improved the level of familial support and the participants' perceptions of social support by family members in the field of physical activity The physical activity performance of the SMS group was better three months after training as compared with that of the control group ($P < 0.001$).	income, body mass index [BMI], type of medication, prior related behaviors, and perceived health status) and experiences questionnaires in three stages (at the beginning of the study, four weeks after the fist visit, and three months later) comprising demographic factors, questions regarding the constructs, and 7-day physical activity recall		

#8	Nundy, S., Dick, J., Solomon, M., & Peek, M. (2013).	Qualitative. Exit interview after 4 weeks the intervention	N=18 18 African-American patients with type 2 diabetes who completed a 4-week text message-based diabetes program from the University of Chicago Primary Care Group	The constant, daily communications reduced denial of diabetes and reinforced the importance of self-management (Rosenstock Health Belief Model). Responding positively to questions about self-management increased mastery experience (Bandura Self-Efficacy). Participants perceived the automated program as a ‘‘friend’’ and ‘‘support group’’ that monitored and supported their self-management behaviors (Barrera Social Support).	Interview for a mobile phone-based diabetes program affecting self-management	Study utilizes a sample of patients who completed a specific text messaging intervention; the results may not generalize to other mobile phone interventions. In particular, the weekly phone calls with the text administrator in the study may have contributed to the high levels of social support perceived by participants. Because the pilot study was relatively brief, the participant perceptions we observed may not generalize to	Level III High/good quality

						longer interventions.	
#9	Nundy, S., Dick, J., Chou, C., Nocon, R., Chin, M., & Peek, M. (2014).	Quasi-experiemtnatl, two-group, pre-post study	Age eighteen or older with type 1 or type 2 diabetes be contacted for recruitment. N= 348. Intervention group = 74 Control group= 274 Primary care setting, University of Chicago's employee health plan and their dependants	Control of HbA1c improved in the treatment group: In the pre period HbA1c averaged 7.9 percent, and in the post period it averaged 7.2 percent (p=0.01). Glycemic control also improved in the subset with poorly controlled diabetes: The average in the pre period was HbA1c of 10.3%, and in the post-period it was 8.5 percent (p= 0.01); No change in HbA1c was observed in the control group. Self-care improved during the study period. The number of days in a seven-day period that	Clinical data on HbA1c, lipid profile, body mass index, and blood pressure for members of both groups from the participants' EHRs. After six months, participants in the treatment group were asked about their satisfaction with CareSmarts using a six-point Likert	lack of randomization and its quasi-experimental design Control group participants may be excluded due to a lack of personal mobile phone or texting capability; or refused to participate. The study's brief duration and lack of long-term follow up; and incomplete data on the control group, including no pharmacy and	Level II High/goodquality

				participants reported following a healthy eating plan increased from 4.5 days to 5.2 days (p =0.03), the number of days they reported monitoring their blood glucose rose from 4.3 days to 4.9 days (p = 0.03), and the number of days they reported practicing foot care increased from 3.6 days to 4.3 days (p = 0.01). Adherence to diabetes medications as measured by the proportion of days covered increased from 83 percent to 91 percent (p = 0.003). Most participants agreed that phone	response scale. Diabetes Self-Care Activities Measure created by Deborah Toobert and colleagues was used to assess the five following areas of self-care practice on a one week scale -healthy eating, fruit and vegetable consumption, exercising, blood sugar testing, and foot care	telephonic survey data.	

				calls from the nurse were helpful for education (64 %) and health care navigation (70 %). The total cost of health care declined by $812 per participant per six months. This reflected a $1,332decline in costs for outpatient, emergency department, and inpatient visits			
#10	Penn, L., Dombrowski, S., Sniehotta, F., & White, M. (2013).	Qualitative sub study interview	n= 15 selected for physical activity increase to the qualitative substudy after 1 year of intervention from N=134 adults aged 40-65 years at elevated risk of type 2 diabetes (Finnish Diabetes Risk Score	After analysis of 15 interview transcripts, researchers found participants' perspectives across different phases (initiating, enacting and maintaining) of the	Individual semi-structured interviews were conducted by the researcher (LP, female research associate) .	Was limited by the small study size and primary focus on successful participant	Level III Good quality

			> 11) to the intervention Community settings where the UK government statistics ranks as 1/10 most socioeconomically deprived areas in England.	behavioral change process. Analysis showed the importance of social influences, as well as the social role and identity both outwit and within the programme. Intentions and goals were also dominant themes across all phases, whereas reinforcement, regulation and decision processes were most evident in the maintenance phase. Participants described complex strategies for maintaining physical activity and	Interviews were completed by 15 participants and lasted between 45 min and 1 h based on relevant qualitative research within the European Diabetes Prevention Study.		

				regulating dietary intake over time. Environmental context and resources (especially monetary costs where people had financial constraints) were important and were linked to the social aspects of engaging in PA.			
#11	Simon, S., Toumpakari, Z., Turner, K., Cooper, A., Page, A., Malpass, A., & Andrews. R. (2018)	Semi-structured interviews were conducted (by AM) at 6-months (face-to-face interview) and 9-months (telephone interview) post-randomization from adults who participated in	N= 30 Thirty patients (n female = 18) were interviewed, comprising 6 from the Usual care (UC) arm (n female = 3), 12 from the Intensive Dietary Advice (ID) arm (n female = 8) and 12 (n female = 7) from the an intensive dietary advice and physical	The diverse motivational experiences of people newly diagnosed with T2DM. Participants who reported relatively dominant controlled motivation experienced initial behavior change but this was often accompanied by internal conflict, frustration and a need for continual external prompting.	Researcher triangulation to identify and describe patient experience. narratives that reflected the motivation at 6-months (face-to-face interview) and 9-months	The follow-up interviews were shorter. More theory-driven follow up interviews would have allowed a more in-depth analysis of motivation change. while we have reported our secondary analysis methods transparently and	Level III High/good quality

		the Early ACTivity In Diabetes (Early ACTID) RCT trial	activity intervention (DPAI) arm.	Applying self-determination theory, researchers identified that many participants reported relatively dominant controlled motivation to comply with lifestyle recommendations, avoid their non-compliance being “found out” or suppress guilt following lapses in behavior change attempts. Such narratives were accompanied by experiences of frustrating slow behavior change progress. More autonomous motivation was expressed as something often achieved over time and reflected goals to improve health,	(telephone interview)	used researcher triangulation to agree our interpretations, due to the lapse between data collection and the analysis, it was not possible to use other strategies, such as member checking	

				quality of life or family time. Motivational internalization was evident and some participants had integrated their behavior change to a new way of life which they found resilient to common barriers.			

Appendix 9: IRB Waived Document

SON Research <sonresearch@email.gwu.edu> (sent by cromaine… Tue, Jun 18, 2019, 10:15 AM
to me

Dear Dr. Allen and Ji,

Regarding the determination worksheet for the project entitled, "The Effects of Diabetes Self-care Management Education Paired with Behavior Change Support Program Using Mobile Technology in Improving Disease Knowledge, Self-care Activities, and
Health Outcomes in Adult Type II Diabetes," a determination has been made that your project does not meet the definition of research. That is, a systematic investigation intended to contribute to generalizable knowledge.

This determination is being made after review of the project documents. The project nature as quality improvement intends to inform internal practice. The project does not aim to inform new theories or external standards of practice. Therefore, further review by the GW Nursing Office of Research or the GW Institutional Review Board is not required (per GW IRB Policy HRP-010, Human Research Protection Program).

Should your project change in any way that it would meet the definition of research, please contact the GW Nursing Office of Research at sonresearch@gwu.edu so we may assist you in proceeding. As a reminder, you are to conduct all projects in an ethical manner regardless of review requirements.

Please do not hesitate to contact me with any questions or concerns regarding this determination.

Kind regards,

Cortni Romaine, PhD Candidate, MS, CIP | *Research Program Associate*
The George Washington University School of Nursing
Member, GW Institutional Review Board

Appendix 11: Letter of Cooperation

School of Nursing
THE GEORGE WASHINGTON UNIVERSITY

nursing@gwu.edu
202-994-7901
nursing.gwu.edu

Date: 01/02/2019

Re: Letter of Cooperation for Muslim Community Center Medical Clinic

Dear. Ji Min

This letter confirms that I, as an authorized representative of the MCC Medical Clinic, allow the above-named Doctor of Nursing Practice student access to conduct quality improvement (QI) related activities at the site, as discussed with the DNP student Ji Min and briefly outlined below, and which may commence when the DNP student provides evidence of IRB approval for the proposed project.

- **DNP Project Study Site(s)**: Medical Clinic

- **Study Purpose:** To study the effectiveness of Diabetic Self-Management Education (DSME) paired with Behavior Change Support Program (BCSP) using mobile technology on diabetes-related behavioral changes and patient outcomes.
- **Study Activities:** DSME paired with ongoing provision of BCSP to encourage maintenance of healthy diabetes-related behavior change. The intervention group will receive ongoing BCSP using mobile technology to support for long-lasting diabetes-related behavioral changes toward a healthier life, as well as their outcomes. For instance, two to three text messages per week, monthly phone calls, and in-house group meetings over three months. Evidence based educational materials will be developed based on various resources from professional organizations such as the American Diabetes Association, the National Institutes of Health, and the National Diabetes Education Initiative. Weekly education contents will be different including general diabetes education, recommended physical activity, dietary change, medication adherence, and preventative screening for diabetes. Patient outcomes will be retrieved by access to eCW.
- **Subject Enrollment:** Subject inclusion criteria are newly diagnosed or chronic type 2 diabetic adults with A1C 7.5% or above. Sample size target is 30-40.
- **The site (s) Support**: Medical Clinic agrees to provide space to conduct study activities. Responsible staff member will measure, record, and retrieve pre- and post-intervention outcomes, from EHR.
- **Data Management:** Changes in self-care management and clinical outcomes will be measured by the patient's reduction of BMI, A1C level, LDL levels, BP using data retrieval from eCW. Diabetes knowledge and Self-care activities will be measured by Michigan Diabetes Research and Training Center's Diabetes Knowledge Test and the Summary of Diabetes Self-care Activities Measure questionnaires. To measure the patient satisfaction with the program, the Diabetes Treatment Satisafcation Questionnaire will be used. Collected data will be stored in password protected folder as well as encryption of Word or Excel files on DNP student's laptop.
- **Other:** The clinic agrees to consider implementing this program if the study ends with significant improvement in patient clinical outcomes
- **Anticipated End Date:** 05/30/2020

We understand that this site's participation will only take place during the active IRB approval period. All DNP project related activities must cease if IRB approval expires or is suspended. I understand that any activities involving Personal Private Information or Protected Health Information require compliance with HIPAA Laws and GWU Policy.

Our organization agrees to the terms and conditions stated above. If we have any concerns related to this project, we will contact Ji Min. For concerns regarding IRB policy or human subject welfare, we may also contact the GWU IRB.

Regards,

School of Nursing

THE GEORGE WASHINGTON UNIVERSITY

nursing@gwu.edu
202-994-7901
nursing.gwu.edu

Signature

4/26/2019
Date Signed

ASIF S. QADRI
Full Name

MEDICAL DIRECTOR
Job Title

medical CLINIC

Appendix 17: DNP Project Approval Signature Sheet

Title: The Effects of Diabetes Self-Care Management Education Paired with Behavior Change Support Program Using Mobile Technology in Improving Disease Knowledge, Self-Care Activities, and Health Outcomes in Adult Type II Diabetes

A Project Presented to the Faculty of the School of Nursing
The George Washington University
In partial fulfillment of the requirements
For the Degree of Doctor of Nursing Practice
By

Ji Min, MSN, CRNP, FNP-C
Name of DNP Student

Approved: Dr. Allen, Cynthia, PhD, APRN, FNP-BC
DNP Primary Advisor

Approved: Dr. Zhou, Qiuping, PhD,
DNP Second Advisor(s)

Approved: Dr. Asif, Qadri, MD
DNP Team Member(s)

Approval Acknowledged:
Director DNP Scholarly Projects

Approval Acknowledged:
Assistant Dean for DNP Program

Date: 04/24/2020

Appendix A: SWOT Analysis

	Helpful To achieving the objective	**Harmful** To achieving the objective
Internal Origin {Attributes of the organization}	**Strengths** • The leadership team is aware of diabetes care issues and strongly support EBP implementation • The organization offers employees' leadership development and professional growth • The QA/I manager will join the project team for the program development and data gathering • Colleagues who are expert in diabetes management will support the program development • The clinic is already providing monthly DSME classes • Continuity of care and communication will strengthen the patient's trust in health care	**Weaknesses** • Only the registered dietitian is involved in DSME • DSME attendees' diabetes control or outcome is not closely monitored • Free Pharmacy Program and Diabetes Management Program are only eligible for Montgomery County residents • Monthly DSME classes are not guaranteed if attendance is less than 13 patients • Older patients may not have access to mobile phone or do not know the text messaging features
External Origin {Attributes of the organization}	**Opportunities** • Collaborating with community healthcare professionals • Securing county grants and funds by improving diabetes management and meeting the performance measure requirements • Expanding the project to other safety-net clinics under the Primary Care Coalition to improve diabetes patient population outcome	**Threats** • Continuity of care and adherence to intervention can be challenging for non-Montgomery County patients due to their financial issues • Competitors provide DSME by certified diabetes educators

Appendix B: Diabetes Care Profile for Medication

Medication

Please, circle your responses.

1. Are you currently taking medication for high blood pressure?

YES NO

2. Are you currently taking medication for high cholesterol?

YES NO

3. What type of diabetes medication? Please, circle all that apply.

ORAL INSULIN BOTH

Appendix C: Descriptive Statistics

Characteristics of the sample and clinical factors at baseline

	Total sample N=14	**Post intervention who completed ONLY biometrics** n=11	**Post- who completed BOTH biometrics and questionnaires** n=7
Variable	Frequency (%)		
Gender			
Male	6 (42.9%)	4 (36.4%)	2 (28.6%)
Female	8 (57.1%)	7 (63.6%)	5 (71.4%)
Age			
<40	3 (21.4%)	3(27.3%)	2 (28.6%)
40-60	5 (35.7%)	3 (27.3%)	2 (28.6%)
>60	6 (42.9%)	5 (45.5%)	3 (42.9%)
Education			
High school or GED or less	8 (57.1%)	6 (54.5%)	4 (57.1%)
Some college	1 (7.1%)	1 (9.1%)	1 (14.3%)
Bachelor's degree	2 (14.3%)	2 (18.2%)	2 (28.6%)
Graduate degree	3 (21.4%)	2 (18.2%)	0 (0%)
Race/Ethnicity			
White	0 (0.0%)	0 (0.0%)	0 (0%)
Black or African American	8 (57.1%)	5 (45.5%)	2 (28.6%)
Native American or American Indian	0 (0.0%)	0 (0%)	0 (0%)
Asian or pacific islander	6 (42.9%)	6 (54.5%)	5 (71.4%)
Hispanic	0 (0.0%)	0 (0%)	0 (0%)
Other	0 (0.0%)	0 (0%)	
Employment			
Unemployed	1 (7.1%)	1 (9.1%)	1 (14.3%)
Part-time	6 (42.9%)	4 (36.4%)	3 (42.9%)
Full-time	6 (42.9%)	5 (45.5%)	3 (42.9%)
Retired	1 (7.1%)	1 (9.1%)	0 (0%)
Marital Status			
Never married	2 (14.3%)	1 (9.1%)	0 (0%)
Married	10 (71.4%)	9 (81.8%)	7 (100%)
Single/Divorced/Widowed	2 (14.3%)	1 (9.1%)	0 (0%)

Currently taking medications for high blood pressure (yes)			
Yes	7 (50.0%)	3 (27.3%)	3 (42.9%)
No	7 (50.0%)	4 (36.4%)	4 (57.1%)
No answer	0 (0%)	4 (36.4%)	0 (0%)
Currently taking medications for high cholesterol (yes)			
Yes	6 (42.9%)	4 (36.4%)	4 (57.1%)
No	8 (57.1%)	3 (27.3%)	3 (42.9%)
No answer	0 (0%)	4 (36.4%)	0 (0%)
Health insurance			
Yes	3 (21.4%)	1 (9.1%)	1 (14.3%)
No	6 (42.9%)	5 (45.5%)	3 (42.9%)
MCares	5 (35.7%)	5 (45.5%)	3 (42.9%)
No answer	0 (0%)	0 (0%)	0 (0%)
Have you ever received diabetes education? Pre-intervention data only			
YES	6 (42.9%)	6 (54.5%)	3 (42.9%)
NO	8 (57.1%)	5 (45.5%)	4 (57.1%)
Type of DM medication			
missing	0 (0%)	0 (0%)	0 (0%)
Not taking meds	0 (0%)	1 (9.1%)	1 (14.3%)
Oral	12 (85.7%)	10 (90.9%)	6 (85.7%)
Insulin	0 (0.0%)	0 (0%)	0 (0%)
Both	2 (14.3%)	0 (0%)	0 (0%)
Have you ever received diabetes education? Pre-intervention data only			
YES	6 (42.9%)	6 (54.5%)	3 (42.9%)
NO	8 (57.1%)	5 (45.5%)	4 (57.1%)
BMI (mean, SD, range) using pounds and feet/inch	29.4 (SD = 4.94), range: 23.95-39.32	29.84 (SD=5.01), range 24.51-39.42	28.35 (SD=5.10), range 24.51-39.42
Normal (BMI <25.00)	3 (21.4%)	2 (18.2%)	2 (28.6%)
Overweight (BMI 25.00-29.99)	5 (35.7%)	5 (45.4%)	4 (57.1%)
Obese (BMI>=30)	6 (42.9%)	4 (36.4%)	1 (14.3%)
HbA1C	8.9 (SD = 1.50), range: 7.1-12.3	8.43 (SD=1.30), range:6.60-10.10	8.47 (SD=1.29), range 6.6-10
LDL mg/dL	91.4 (SD = 22.36), range: 50-139	91.0 (SD=26.49), range 54-144	92.0 (SD=28.61), range 56-144

Mean systolic BP	121.3 (SD = 17.50), range: 100-150	122.6 (SD=15.05), range 98-148	126.57 (SD=17.46), range 98-148
Mean diastolic BP	72.4 (SD = 10.08), range: 60-88	72.36 (SD=10.15), range 54-84	73.14 (SD=9.72), range 54-84
Do you check FBG?			
YES	11 (78.6%)	7 (63.6%)	7 (100%)
NO	3 (21.4%)	0 (0%)	0 (0%)
No answer	0 (0%)	4 (36.4%)	0 (0%)
How many days a week do you check FBG?	2.4 (SD = 2.34), range: 0-7	2.6 (SD=2.50), range: 0-7	3.14 (SD=2.12), range 1-7

Appendix D: Data Analysis Plan

Question: has the intervention improved patients' diabetes knowledge compared to the baseline?

- DV: knowledge score
- IV: intervention (pre versus post)
- Analysis: Paired t-test

Question: Is there a difference in patient satisfaction post intervention?

- Variable: Satisfaction
- Analysis: Descriptive statistics

Questions: Is there a change in biometrics from pre-test to post-test?

- DV: biometrics
- IVs: time (pre vs post)
- Analysis: paired t-test

Question: Is there a change in self-care activities from pre-test to post-test?

- DV: Self-Care Activities
- IVs: time (pre vs post)
- Analysis: Paired t-test

Pre and post biometric and diabetes knowledge and self-care activities

	Intervention group		Statistics and P values
	pre	post	
BMI	Mean (SD)	Mean (SD)	Paired t-test
BP	Mean (SD)	Mean (SD)	Paired t-test
LDL	Mean, mg/dL	Mean mg/dL	Paired t-test
A1C	Mean % (SD)	Mean % (SD)	Paired t-test
Diabetes knowledge total	Mean (SD)	Mean (SD)	Paired t-test
Diabetes self-care activities total	Mean (SD)	Mean (SD)	Paired t-test

The categories of Diabetes Self-Care Activities Measure (SDSCA)

	Intervention group		
	Pre	post	Test and p values
Diet	Mean # of days	Mean # of days	Paired t-test
Exercise	Mean # of days	Mean # of days	Paired t-test
Blood-glucose testing	Mean # of days	Mean # of days	Paired t-test
Foot care	Mean # of days	Mean # of days	Paired t-test
Smoking status	Yes/no,	Yes/no,	McNeimar's test
Number of cigarettes per day			Paired t-test
Medication	Mean # of days	Mean # of days	Paired t-test

Appendix E: Evaluation Planning Matrix

Goal	Objectives	Evaluation Questions	Benchmarks	Methods
Overall Program				
Improve clinical outcomes of diabetes patients	A reduction in biometrics such as HBA1C (<8%), BMI, BP (<140/90), and LDL levels (<100)	Does BCSP improve patients' diabetes clinical outcome measures compared to baseline?	The patient will have a reduction in biometrics measures compared to baseline	Analysis of biometric pre- and post-data
Improve diabetes knowledge and self-care activities	Patients have at least 20% higher score on knowledge and self-care activities tests	Does BCSP improve patients' knowledge and self-care activities compared to baseline?	The patient will have improved scores (at least 20%) on knowledge and self-care activities tests compared to baseline	Analysis of pre-test and post-test scores on The Summary of Diabetes Self-Care Activities Measure and Michigan Diabetes Research and Training Center's Revised Diabetes Knowledge Test
Increase patient satisfaction	Patients are satisfied with the intervention and would recommend to others	Do patients satisfy with BCSP and recommend the program to others?	XXX	A sum of eight items from the Diabetes Treatment Satisfaction Questionnaire at the end of the project
Process				
Successfully involve stakeholders	The project team verbalize understanding of patient's confidentiality and outcome measure protocol Patients verbalize understanding of	Do the project team members fully understand outcome measure protocols and patient's confidentiality? Do patients fully understand the requirements for biometric measures?	To obtain accurate outcome data and protect patient's confidentiality	The project's aim, goals, protocols, and expected outcomes will be discussed during a 30-minute team meeting, and the team members will sign the form Requirements, risks/harms, and the benefit of the study will be discussed before signing the consent form

Goal	Objectives	Evaluation Questions	Benchmarks	Methods
	requirements for biometric measures			
Identify barriers	To provide detailed information and incorporated into a plan to enforce a participant's commitment to the project	Do the participants fully understand about the project, including timelines and required activities, and their responsibilities?	To reduce the likelihood of participant withdrawal	Requirements, risks/harms, and the benefit of the study will be discussed before signing the consent form. In the end, the withdrawal rate and reasons for the decision to stop participating in the study will be reviewed
Structure				
Establish effective scheduling methods	Establish a scheduling method to accommodate the intervention	Is the planned project timeline useful and practical to implement the intervention?	To overview and monitor the performance of the project from the beginning to the end	The planned timeline table will be provided to both participants and the project team members, so all stakeholders understand the project timeline.

Appendix F. Behavior Support Text Message Examples

Educational Topics	Contents for Texts	Text formats	Sources
Introduction	• Greeting	• Thanks for participating in the study. We welcome you and look forward to working together!	
Diabetes Information	• General diabetes • Chronic complications • Medication adherence • Diabetes and alcohol or smoking • Importance of self-management	• Diabetes is a disease in which the body is unable to properly use sugar and store it. When sugar (glucose) backs up in the bloodstream, it causes rising blood sugar too high. Type 2 diabetes results when the body does not produce enough insulin or is unable to use insulin properly. People ages over 40, overweight, and have a family history of diabetes are at higher risk of developing diabetes. • Good morning! Do you know the symptoms that people with diabetes frequently experience? Here are a few examples; Being very thirsty, frequent urination, weight loss, increased hunger, blurry vision, tingling or numbness in the hands or feet, frequent skin, bladder, or gum infections, wounds that do not heal, and extreme unexplained fatigue. • Having unmanaged blood sugar in your body for a long period can cause health problems, such as heart disease, nerve damage, eye problems, and kidney disease. • **A** is for A1C, or HbA1c, which is a test that measures blood glucose control over the past two to three months. The A1C target for most people is under 7%. A 1% reduction in mean A1C levels has been found to be associated with risk	• Joslin Diabetes Center • Joslin Diabetes Center • National Institute of Diabetes and Digestive and Kidney Diseases • Canadian Diabetes Association

Educational Topics	Contents for Texts	Text formats	Sources
		reductions of: 37% for microvascular complications, 21% for death related to diabetes, and 14% for heart attack. **B** is for blood pressure. Nearly 2 out of 3 people with diabetes have high blood pressure. For most people with high blood pressure and diabetes, blood pressure levels should be <130/80 mm Hg. Diabetes patients should aim for blood pressure readings of less than 130/80 mmHg to avoid diabetes-related complication such as kidney disease. Lifestyle changes, healthy eating, physical activity, losing weight, and cutting back on salt and caffeine can help positive effect. **C** is for cholesterol. Total cholesterol, LDL and triglycerides should be monitored. Having elevated LDL cholesterol (bad cholesterol) levels for a significant period can damage arteries because it causes the formation of plaque in the blood. LDL reading should be less than 100 or less than 70 if you have diabetes and heart disease. **D** is for a healthy diet and, if appropriate, drug therapy. **E** is for exercise. **S** is for stop smoking. Smoking doubles the risk of heart disease in people with diabetes. diabetes who smoke are more likely to develop microvascular complications, especially nephropathy (kidney disease) and neuropathy (numbness and tingling sensation), faster. Specifically, both micro- and macroalbuminuria progress more rapidly in current smokers when compared to those who quit and those who never	

Educational Topics	Contents for Texts	Text formats	Sources
		smoked. Also, the incidence of neuropathy is 2.2 times higher in smokers versus nonsmokers. • Hi (Name)! The oral medications along with diet and exercise, will help you to keep your blood glucose in a healthy range. Eventually, it prevents chronic complication. Setting medication alarms remind you to take your medicine every day! • Alcohol should be limited to 2 drinks a day. A drink is defined as a 12 oz beer, a 4 oz glass of wine or a 2 oz glass of dry sherry or 1.5ox of a distilled beverage such as whiskey, rye, vodka or gin. Do not forget! Alcoholic beverages have calories without any nutritional value. Also, never drink on an empty stomach because it can make your blood sugar drop. • When blood sugar is high, the stage is set for germs and fungi to grow. If you have diabetes, you are more prone to infections. This is true for a couple of reasons. When blood sugar is high, the stage is set for germs (“bacteria”) and fungi to grow. And, with high blood sugar, your immune system does not work as well. It is not as good at fighting off infection. There are some common places on the body to look out for infections. • Yeast infection (called “Candida”) in the groin or vagina • Urinary Tract • Gums • Feet • Wounds Your doctor may give you medicine (called “antibiotics” or "antifungal") to fight the germs.	• Joslin Diabetes Center • Joslin Diabetes Center

Educational Topics	Contents for Texts	Text formats	Sources
		It is best to see a doctor sooner rather than later. You should treat infections right away. • Diabetic patients who smoke have higher risks for a serious complication, including heart and kidney disease, poor blood flow in the legs and feet which can lead to infections, ulcers, and possible amputation, blindness, and lower legs numbness, pain, and poor coordination. People with diabetes who quit smoking have better control of their blood sugar levels. You can have free help to quit, call 1-800-784-8669 or visit CDC.gov/tips. • Having elevated LDL cholesterol (bad cholesterol) levels for a significant period can damage arteries because it causes the formation of plaque in the blood. LDL reading should be less than 100 or less than 70 if you have diabetes and heart disease. • Diabetes patients should aim for blood pressure readings of less than 130/80 mmHg to avoid diabetes-related complication such as kidney disease. Lifestyle changes, healthy eating, physical activity, losing weight, and cutting back on salt and caffeine can help positive effect.	• Joslin Diabetes Center • Centers for Disease Control and Prevention • Joslin Diabetes Center
Healthy eating	• Heart-healthy diet • Tips for healthy eating • Eating out • Understanding food labels	• A healthy meal plan for diabetes is generally the same as healthy eating plans for anyone. Consume food low in saturated fat, moderate in salt and sugar, lean protein, non-starchy veggies, whole grains, and fruits. • Tips for healthy eating! Avoid breaded or fried foods or foods in heavy sauces. You can try grilled or broiled fish or poultry without butter.	• American Diabetes Association • Joslin Diabetes Center

Educational Topics	Contents for Texts	Text formats	Sources
		• Are you dining out? Choose a restaurant with a large selection of healthy items. Here again, watch your portion sizes! Order an appetizer for the main course, eat half at the restaurant, and take the rest home. • A portion is how much food you choose to eat at one time while a serving size is the amount of food listed on a Nutrition Facts or food label. The food label is a quick way to find the number of calories and nutrients such as fat, protein, and sugar. Did you notice the updated food label also includes information about "added sugar?" Please, view the image file. (picture 1 below the table) • Many Thanksgiving dishes are carbohydrate-heavy, posing a danger for people with diabetes. Even side dishes like cranberry sauce are usually not diabetes-friendly. people with diabetes might also have high blood pressure and high cholesterol. This can be problematic when a Thanksgiving meal has lots of high-fat and sodium-rich foods. Keep your consumption in moderation & Try to have one plate—and no seconds! Keep your portion sizes very low for these high-carb favorites: • Mashed potatoes • Candied yams • Sweet potato casserole Or avoid them altogether The same goes for stuffing.	• Joslin Diabetes Center • National Institute of Diabetes and Digestive and Kidney Diseases • Penn Medicine.org

Educational Topics	Contents for Texts	Text formats	Sources
		If you have any, make it just a small amount, because it's very high in carbohydrates. Opt for diabetic-friendly recipes and simple food substitutions Try to have a turkey roasted instead of fried. And keep portion sizes appropriate When you prepare foods, you can sautéed spinach rather than creamed spinach. And if there's going to be a salad, put the dressing on the side. If you want to have appetizers, stick to basic vegetables like fresh celery and carrots. These foods are not carb-heavy, and they can fill you up a bit before the meal.. more greens include salad, green beans, asparagus, or spinach. These are less starchy vegetables It's okay to have a small amount of pumpkin pie, but try to eat fewer carbs during the meal to make room for dessert • **Before you leave for vacation** • Get extra prescriptions and a letter from your doctor explaining that you have diabetes. • If you need immunization shots, plan to get them 3 to 4 weeks before your vacation. Some of these shots can upset your blood sugar levels.	• Cleaveland Clinic

Educational Topics	Contents for Texts	Text formats	Sources
		What should I bring with me when I travel? • Bring your doctor's name and phone number and keep them with you at all times. • Bring a list of current medicines and keep it with you at all times. • Always carry and wear medical identification that states you have diabetes. • Keep medicines, syringes, and blood sugar testing supplies in your carry-on luggage. Do not check these supplies with your luggage in case it is lost. Remember, the cargo hold is not heated or well insulated, so medicine and supplies can be damaged. • Take enough medicines and medical supplies to last an extra week in case you get stranded or stay longer than you planned. • Have a traveling companion carry some of your medical supplies, if possible. • Always carry some type of sugar source in case you develop hypoglycemia (low blood sugar). • Inform the airlines and cruise ships in advance that you have diabetes. Most airlines and cruise ships will provide special meals. • Test your blood sugar more often than usual. Changes in meal patterns, activity levels, and time zones can affect your blood sugar. **How do I take care of my feet while traveling?** • Pack at least 2 pairs of shoes so that you can change shoes often. Changing shoes helps prevent blisters and sore pressure points.	

Educational Topics	Contents for Texts	Text formats	Sources
		• Pack comfortable shoes, socks, and a first-aid kit to treat minor foot injuries. • Do not go barefoot. Instead, wear shoes that are specially made for ocean or beach walking. Protect your feet at all times when you are walking by the pool, in the park, and on the beach, or swimming in the ocean. • Do not wear open-toe shoes, including sandals, flip-flops, or others. You increase your risk for injury and infection when your toes are exposed. • Follow your daily foot-care regimen.	
Physical activity	• Recommended physical activity • Benefits of physical activity	• How are you (name)? Just a quick reminder. Recommended physical activity and exercise for diabetes include three or more minutes of light activity such as walking, leg extensions or overhead arm stretches every 30 minutes during the prolonged sedentary time • Good morning! There are ways to add extra activity to your daily routine. Increase daily activity by spending less time in front of a TV or computer. Try simple physical activities each day by walking around while you talk on the phone or during TV commercials, parking at the far end of the shopping center parking lot and walk to the store, taking the stairs instead of the elevator, or making your family outings active like a family bike ride. • Hi (name)! Did you know that walking at a brisk pace also may offer health benefits? It helps to lower your risk of high blood pressure, high cholesterol, heart disease, and type 2 diabetes! Also, a brick paced walking strengthens your	• American Diabetes Association • National Institute of Diabetes and Digestive and Kidney Diseases • National Institute of Diabetes and Digestive and

Educational Topics	Contents for Texts	Text formats	Sources
		bones and muscles and improve your fitness. You should try it! It will lift your mood.	Kidney Diseases
Weight management	• Understanding the Body Mass Index • Weight loss and diabetes	• Hi there! Body Mass Index is based on a calculation of your weight and height and tells you about a healthy weight range for you. For adults 20 years old and older, BMI between 18.5-24.9 is normal, between 25-29.9 is overweight, and 30 or above is obese. You can use the tool on the American Diabetes Association website. • Weight loss can help your body use insulin better. This helps your body to control blood sugar levels. Your diet will be basically the same as the healthy heart diet. It is also like the diet that reduces the risk of certain cancers. You will need to be mindful of your calorie intake to reach your desired weight. You will also have to restrict the sweets in your diet. The ADA (American Diabetes Association) has some suggestions for the start of your weight loss program: • Cut 500 calories from what you eat each day. • Have a balanced diet with a mixture of nutrients. • Limit the fats in your diet. They should be less than 30% of the calories you eat each day. Less than 10% of calories should come from “bad” fats (called “saturated fats”). • Eat starches and sugars that take longer to digest (called “complex carbohydrates”). About 50% of calories you eat should come from these. Examples are: fresh vegetables; grains; lentils, beans, and	• American Diabetes Association • American Diabetes Association

Educational Topics	Contents for Texts	Text formats	Sources
		other legumes; whole grain breads; fresh fruits. But limit fruit juices because they have a lot of sugar. Another change to make in your diet is the pattern of your meals. For example, you should eat smaller and more frequent meals. Small meals with a lot of protein or certain snacks ("complex carbohydrate" snacks) are good too. These changes limit how much sugar your body breaks down at one time. This helps to control blood sugar levels. Finally, you should get more active. Exercise and diet help you control your blood sugar. • Losing weight too quickly is not good for your health. Try to lose a half to 2 pounds per week by consuming 250-1,000 calories less from what you would normally eat in a day.	• American Diabetes Association
Monitoring diabetes	• Understanding fasting glucose and A1C levels • Hypertension and hyperlipidemia control in diabetes care • Preventative screening	• Hi (name)! A1C is a measure of the average amount of your blood sugar over the past 3 months. Even though A1C targets are personalized, the general A1C target for adult's diabetes is less than 7%. If you get the number closer, the better your chances for preventing other health problems such as foot sores, eye disease, and kidney disease. Do not forget; the blood sugar goal is less than 80 to 130 mg/dL before a meal. • Some patients do not realize that they have foot problems because they have decreased feeling in their feet. Make sure checking your feet each day to detect problems early. Take off your shoes->	• American Diabetes Association and National Diabetes Education Initiative • National Institute of Diabetes and Digestive and

Educational Topics	Contents for Texts	Text formats	Sources
		check between your toes. Look for problems for cuts, swelling, ingrown toenails, and calluses • People with diabetes are at higher risk for a variety of foot health problems. A diabetic foot exam checks people with diabetes for these problems, which include infection, injury, and bone abnormalities. Nerve damage, known as neuropathy, and poor circulation (blood flow) are the most common causes of diabetic foot problems. Neuropathy can make your feet feel numb or tingly. It can also cause a loss of feeling in your feet. So if you get a foot injury, like a callus or blister, or even a deep sore known as an ulcer, you may not even know it. People with diabetes should get a diabetic foot exam at least once a year. You may need an exam more often if your feet have any of the following symptoms: Tingling Numbness Pain Burning sensation Swelling Pain and difficulty when walking • Did you know that type 2 diabetes should have a comprehensive eye exam at the time of diagnosis? If any level of diabetic related eye problem is present, the eye exam should be repeated at least annually by an ophthalmologist.	Kidney Diseases • National Institute of Diabetes and Digestive and Kidney Diseases • American Diabetes Association
Maintaining contact with PCP	• Importance of keeping contact with your PCP	• People with well-controlled diabetes by healthy eating and lifestyle changes still need regular health checkups and tests. By keeping contact with your doctor, you can ask your health	• National Institute of Health-MedlinePlus

Educational Topics	Contents for Texts	Text formats	Sources
	• How to get prepared for your PCP visit	concerns, learn more about diabetes like how you can do to keep your blood sugar in the target range. • Before your PCP visit, please bring your glucose reading logs and current medications. Don't forget to check if your PCP asked you to do blood tests before the follow-up visit. Also, write down your concerns that you want to discuss! • If you have diabetes, you have an important role in your own medical care and monitoring your blood sugar (glucose) level is a key part of this. Although diabetes is a chronic condition, it can usually be controlled with lifestyle changes, medication, and self-care measures. The main goal of diabetes treatment is to keep your blood sugar levels in the target range. Checking your blood sugar is one of the best ways to know how well your diabetes treatment plan is working. Your health care provider will periodically order a blood test to check your current blood sugar levels and glycated hemoglobin (A1C). The A1C test gives an overall sense of how blood sugar levels are controlled since it measures your average blood sugar level of the past two to three months. However, in order to most effectively manage your diabetes and adjust your treatment approach as needed, you will also need to check your own blood sugar levels on a daily basis.	• Mayoclinic.org

Educational Topics	Contents for Texts	Text formats	Sources
		In addition, patients must take medications as prescribed. The full benefits of medications can be achieved only if the medication regimen is followed as directed. Improving medication adherence can have a greater impact on patient outcomes than can a specific medication alone.	
Emotional support and motivation	• Managing stress • Goal-setting for a healthy life	• Maintain both physical and emotional health is necessary for good diabetes management. When you are under stress, levels of many hormones are increased, which effects are storing energy such as sugar and fat for your body. As a result, your blood sugar goes up! Sit or lie down without crossing your legs and arms. Take in a deep breath. Then push out as much air as you can. Following this breathing pattern with relaxed muscles while breathing out. Repeat these breathing exercises for 5 to 20 minutes at a time. • Emotions can influence what, when, and how much you eat. Think about the time you were under much stress and craved for sweets! Situations can trigger certain negative emotions to prompt eating. Identify any emotions or situations that trigger you to eat, such as afraid, angry, anxious, hate, insecure, lonely, worried, and bored. It is important to do a quick emotional check if you want food because you are hungry or to fill an emotional need. You can make a list of other things to do to fulfill an emotional need. For example, calling a friend, taking a walk,	• American Diabetes Association • American Diabetes Association

Educational Topics	Contents for Texts	Text formats	Sources
		drinking some water or zero-calorie beverage, or doing a few yoga stretches. • Whether or not you just found out you have diabetes or you have had diabetes for a while, you may experience intense feelings. People with diabetes are more likely to have mental health issues like depression and anxiety. **Diabetes distress**. The constant work of managing diabetes can pile on top of life's other responsibilities. Sometimes, you may feel like you need a vacation from it. Recently, doctors have given this burden a name: diabetes distress. It's more than just worry. It's the toll diabetes has on your mental health: a mix of anxiety, frustration, depression, stress, and more. Everyone with diabetes runs into it. But if it's constant and you feel like you're getting burned out, it's a problem. **Learn as much as possible**. Information is power. Understanding your condition and how to manage it will let you see solutions where you first saw concern or confusion. **Make a plan**. Set goals for things like healthy eating, exercise, and learning. A good plan puts you back in control. Break the work into smaller pieces to make it less overwhelming. **Write about it.** A journal can help organize your thoughts and recognize emotional triggers. For	• WebMD

Educational Topics	Contents for Texts	Text formats	Sources
		example, you might realize you're upset over how diabetes changes your social life. **Reach out**. Having a serious condition can make you feel cut off from the world. Seek out family, friends, or a support group, and talk to them honestly about your feelings.	
		• You will need to take many small steps to lose weight. Setting a few smaller realistic goals at a time is very important. Think about what behavior you want to change, and how often you want to do this? Here are some examples. Eating goal- 4 days each week, I will eat an apple instead of ice cream as my evening snack. Physical activity goal- 5 days each week, I will take a 30-minute walk during my lunch hour since I don't' really need the whole hour to eat.	• American Diabetes Association
		• **Tips to Improve Your Emotional Health** o **Exercise** often to lower depression, anxiety, and stress. Yoga, the gym, or a simple walk in nature can all help. o **Get enough sleep.** Everything's harder when you're tired. Create a nightly routine and get to bed at a good time. o **Nix the blame game**. No one's perfect. If you mess up, go easy on yourself. o **Reward yourself**. Find healthy ways to treat yourself so it doesn't feel like work all the time. Reward yourself when you meet goals.	• WebMD

Educational Topics	Contents for Texts	Text formats	Sources
		○ **Check your plan.** Make sure your plan works for you and not the other way around: ○ **Adjust your goals.** If you keep missing your goals, maybe you set the bar too high. Dial it back and find easy wins to build on. ○ **Go small.** Big, sweeping changes might feel good to make, but they're hard to pull off. Go for small changes instead and build good habits. ○ **Try mindfulness.** Mindfulness and relaxation can help, too. ○ You can: ○ Let it be. When you fight your feelings, you only feed the beast. Remember that your moods will pass. ○ Learn relaxation techniques. From deep breathing to meditation, try new ways to keep calm. ○ Practice gratitude. It may sound corny to some, but it works. Think about what you're thankful for, and your mood can shift • The New Year, 2020 is a perfect time to look at your diabetes to-do list and focus on areas that perhaps you are overdue or can improve on. 1. **SET REALISTIC TARGETS** 2. **STOP FEELING LIKE YOU'RE ALONE** 3. **IMPROVE HBA1C READING** 4. **GO EASY ON PROCESSED FOOD** 5. **FIND FUN EXERCISE**	• National Institute of Diabetes and Digestive and Kidney Diseases

Educational Topics	Contents for Texts	Text formats	Sources
		6. **EAT LESS CHOCOLATE FOR HYPOS** o Annual To-Do List: 1. Annual Flu Shot and pneumonia vaccine 2. Annual comprehensive eye exam 3. Comprehensive foot exam with a podiatrist (at least annually, but frequency varies per individual) 4. Visit with the Dentist (every 6 months) 5. Blood Pressure at each visit 6. Labs: Renal Function test- Creatinine/GFR, Lipid Panel (Cholesterol, LDL, HDL, Triglycerides), HgbA1c (every 3 months, or as directed) Goal is 7% 7. Quit smoking 8. Follow up with any specialists or appointments that may be overdue (dietitian, diabetes educator, endocrinologist, mental health providers) 9. Maintain a healthy weight	

Appendix G: Informed Consent Form

THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

Study Assigned Consent Version #/Date: **GW OHR Document Revision Date: 04Jan2019**

Informed Consent for Participation in a Research Study

Title of Research Study: *The Effects of Diabetes Self-care Management Education Paired with Behavior Change Support Program Using Mobile Technology in Improving Disease Knowledge, Self-care Activities, and Health Outcomes in Adult Type II Diabetes*
Investigator: Ji Min, George Washington University, School of Nursing

Key Information:

You are being asked to take part in a research study about … (include general description of study). This page will give you key information to help you decide whether or not you want to participate in this study. More detailed information can be found on the next pages. Please feel free to ask the research team questions during the consent process, and use the contact information on this form to ask questions later.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

By doing this study, we hope to learn about the effectiveness of Diabetes Self-care Management Education class coupled with mobile technology support program in diabetes knowledge, self-care activities, and disease control. You will receive ongoing Mobile technology support from the healthcare team. The program consists of two face-to-face sessions, two to three weekly texts, and three-monthly phone coaching sessions between the diabetes classes.

WHAT ARE THE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The potential benefits to be derived from the research could be gaining knowledge on diabetes self-care management and disease control with diabetes class with an added mobile technology support program. For a complete Description of benefits please refer to the Detailed Consent.

WHAT ARE THE REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The potential emotional risks may include increased pressure and stress regarding being a participant in the research study besides an individual's health status, such as being diagnosed with diabetes. For a complete Description of risks please refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

You do not have to take part in this research. It is your choice whether or not you want to take part in it. You can agree to take part and later change your mind. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled to.

WHAT IF YOU HAVE QUESTIONS OR CONCERNS?

The person in charge of this study is Ji Min. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: 202-669-4455 or jimin@gwu.edu

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.
- You have questions about your rights as a research subject.

Informed Consent for Participation in a Research Study

Detailed Consent Form:

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are type II diabetes patients aged over 18 with Hemoglobin A1C (A1C) 7.5% or above and own a text message-capable mobile phone without physical disabilities affecting vision or walk or currently being on treatment for psychiatric disease or cancer.

What should I know about a research study?

- Someone will explain this research study to you. You may ask all the questions you want before you decide whether to participate.
- Participation is voluntary; whether or not you take part is up to you.
- You can agree to take part and later change your mind.
- Your decision not to take part or to stop your participation will not be held against you.
- Your decision will not affect the medical care you receive from GW. If you decide not to take part, you can still receive medical care from GW.
- You may take this document home to read or to discuss with your family members or doctor before deciding to take part in this research study.

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who can I talk to if I have questions?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Principal Investigator at 202-669-4455 or via email at jimin@gwu.edu.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.
- You have questions about your rights as a research subject.

Why is this research being done?

The purpose of this study is to assist adult type 2 diabetes patients to gain health information, disease management knowledge, and self-care practices through Diabetes Self-care Management Education class paired with ongoing Behavior Change Support Program Using Mobile Technology. Therefore, individuals can have better self-care behaviors, disease knowledge, and diabetes control with a greater reduction in Body Mass Index (BMI), Blood Pressure (BP), A1C and Low-Density Lipoprotein (LDL) cholesterol levels. This research is conducted to improve diabetes care experience and outcomes because comprehensive diabetes care management in the primary care setting is challenging due to the continuous care management process, lack of communication, and support needs for patients. The potential benefits to be

participating this research could be gaining knowledge on diabetes self-care management and disease control with an added behavioral change support program. Additionally, the research study would benefit improving patient-centered quality of diabetes care. The important procedures for this research study are monitoring BMI, BP, A1C, and LDL cholesterol levels from blood tests, as per usual diabetes care.

How long will I be in the study?

We expect that you will be in this research study for three months.

How many people will take part in this research study?

We expect about 35 people will take part in the entire study.

What happens if I agree to be in this research?

The research will be conducted in the Muslim Community Center Medical Clinic in Montgomery County, Maryland. The research will begin in September 2019 and end in the last week of December. The participants will receive usual diabetes care such as medical visits, tests, and monthly diabetes class with added mobile technology support program. The mobile technology support program includes two weekly texts, three monthly phone call coaching between the diabetes class and two face-to-face sessions to provide ongoing support through open communication (see Table 1: Standard Protocol: Project Timeline). The subjects will be asked to complete questionnaires for demographic data, diabetes knowledge, and self-care activities two times, in the begging and after three months at the end of the program. Blood will also be drawn twice to monitor diabetes control for a three-month interval, as per usual care. The first face-to-face meeting will be conducted 1 to 2 weeks before the beginning of the program for orientation at the clinic. The second face-to-face wrap-up meeting will be conducted in week 13 at the clinic. Participants will receive two text messages via SMS text or within the TigerConnect application either on Wednesday or Saturdays for the next 12 weeks. Monthly phone call coaching will be delivered either on Wednesday or Thursday (except on Thanksgiving day) in week four, eight, and twelve of mobile technology support program implementation. Participants will attend the diabetes class in week two, six, and ten. The participants will have contact with the healthcare team at least every two weeks to communicate about diabetes care.

Informed Consent for Participation in a Research Study

Table 2: Standard Protocol: Project Timeline

STUDY PERIOD																	
TIMEPOINT	Enrollment		Intervention												Evaluation	Closeout
ENROLLMENT	0-90 days prior	1-2 weeks prior	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12	Weeks 13-24	> 1 Year
Eligibility Screen																
Informed Consent																
Staff Meeting																
INTERVENTIONS																
Face-to-Face Meeting																
BCST-MT Texting																
Phone Call Coaching																
DSME Class																
ASSESSMENTS																
Baseline · The Diabetes Care Profile Section I- Demographics and Section III-Education/Advice plus Medication · The Summary of Diabetes Self-Care Activities Measure · Revised Diabetes Knowledge Test · Biometric data: A1C, BMI, LDL, BP																
Outcome variables · The Summary of Diabetes Self-Care Activities Measure · Revised Diabetes Knowledge Test · Diabetes treatment satisfaction questionnaire · Biometric data: A1C, BMI, LDL, BP																
Gift cards distribution																

Informed Consent for Participation in a Research Study

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for the day-to-day management of diabetes with daily self-care activities such as medication adherence, engaging in regular physical activity, and recommended diet. The project timeline table provides a brief view of planned events. You should take responsibility for doing blood tests, attending group meetings, and communicating with the project team.

What happens if I agree to be in research, but later change my mind?

You may refuse to participate, or you may discontinue your participation at any time without penalty or loss of benefits to which you would otherwise be entitled.

If you decide to leave the research, contact the investigator so that the investigator can orderly terminate you from the research. You will meet the investigator to discuss reasons to end the participation in the study and fill out the Request to Withdraw from a Research Study letter with signature.

Is there any way being in this study could be bad for me?

The risks and discomforts associated with participation in this study are not greater than those ordinarily encountered in daily life or during the performance or routine physical or psychological examinations or tests.

The probability of anticipated harms and risks in the research study include possible physiological, emotional, and economic burden. You may have physiological harm from blood draw such as bruising, pain, and possibly a syncopal episode. These are possible side effects of blood test that you could have encountered at any other time.

Emotional risks may include increased pressure and stress regarding being a participant in the research study besides an individual's health status, such as diagnosed with diabetes. You will receive all the study information and have the opportunity to ask questions anytime by contacting the investigator. Additionally, participants will receive continuous support and advice regarding diabetes care management from healthcare professionals throughout the study.

Considering the clinic's population, the economic risks of the study subjects are anticipated. All patients who are diagnosed with diabetes and regardless of the study participants are responsible for co-payment, transportation costs, healthy diet grocery shopping, medications or other medical equipment that are required for their diabetes care. Each clinic visit and procedure will be billed to uninsured participants, and insured subjects may require a co-payment, as per usual. Low-income Montgomery County may be eligible for free medical equipment such as glucometers or blood pressure machines as well as several diabetic medications. The clinic also provides a free shuttle bus on weekdays for all patients who live in the Silver Spring area. Nevertheless, the study is intended to provide added behavior change support for participants using mobile technology adjunct to usual ongoing diabetes care. Thus, the research may not involve actual, significant additional costs to an individual with planned intervention other than text-messaging fees or no costs if using free mobile texting applications.
Taking part in this research study may lead to added costs to you at least $0 to the most $10 depending on your text plans.

Informed Consent for Participation in a Research Study

What happens if I believe I am injured because I took part in this study?

The researchers have taken steps to minimize the known or expected risks. In spite of all precautions, you still may experience medical complications or side effects from participating in this study. You should promptly notify the study doctor in the event of any illness or injury as a result of being in the study.

If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment from GWU Hospital and/or the GWU MFA or through your physician or treatment center of choice. Care for such injuries will be billed in an ordinary manner to you or your insurance company.

You will not receive any financial payments from GWU, GWU Hospital and/or the GWU MFA for any injuries or illnesses. You do not waive any liability rights for personal injury by signing this form.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include gaining knowledge on diabetes self-care management and disease control with an added behavioral change support program. Other potential benefits of participating in this research would be a reduction in A1C, cholesterol levels, blood pressure, and weight.

What happens to my information collected for the research?

To the extent allowed by law, we limit your personal information to people who have to review it. We cannot promise complete secrecy. The IRB and other representatives of this organization may inspect and copy your information. There are some limitations on confidentiality based on possible legal issues that your information may be disclosed to appropriate authorities. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases.

How will my privacy and health information be protected?

The Health Insurance Portability and Accountability Act (HIPAA) requires that researchers and health care providers protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions, or the provision of health care. If you agree to participate in this research, protected health information will be used and shared with others for purposes of the study. Below is more detailed information about how your health information will be shared and protected. By signing this form, you are allowing the people and groups that are listed in the next paragraphs to use your health information for this research study. Your information will only be used or shared as explained in this authorization form

The use and release of protected health information is for the purpose of collecting data for this study.

Protected Health Information to be shared:

- Biometrics data: Body Mass Index, Blood Pressure, A1C, LDL cholesterol
- Demographic data: Diabetes Care Profile
- Answered questionnaires: Revised Diabetes Knowledge Test, Self-Care Activities Measure, Diabetes Treatment Satisfaction Questionnaire

Informed Consent for Participation in a Research Study

Who may disclose your protected health information: The researcher and the other members of the research team may obtain your individual health information from:

Clinics: The Muslim Community Center Medical Clinic

And from hospitals, clinics, health care providers, and health plans that provide health care to you during the study

By signing this form, you allow the use, sharing, copying, and release of your protected health information in connection with this study by:

- The members of the research team;
- Other healthcare providers such as labs which are part of the study;
- A safety monitoring board {include only if applicable};
- Institutional officials who are responsible for compliance;

Some of the tests in this study would have been done as part of your regular care. These test results will be used both to treat you and to complete this research. The test results will be recorded in your medical record. These study results will be included in your medical record. Results of tests and studies done solely for this research study and not as part of your regular care will also be included in your medical record.

Once your health information has been disclosed to others outside of the medical practices, the information may no longer be covered by the federal regulation that protects privacy of health information.

Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your health information, you may not take part in this study because your health information is needed in order to conduct this study.

This Authorization does not have an expiration date.

However, you may cancel this authorization at any time. Even if you cancel this authorization, the researchers may still use the protected health information they already have about you; however, no new health information or new biological specimens will be collected from you after you cancel your permission.

To cancel your permission, you will need to send a letter to Ji Min stating that you are canceling your authorization. This letter must be signed and dated and sent to this address:

Ji Min

Are there any costs for participating in this research?

You are responsible for paying your lab tests and co-payment fee. However, the costs of clinic visits and blood testing will be the same as usual diabetes care for study participants. Depending on your text message plans and mobile carrier, you could be charged differently. You will be charged ranging from $0.05 to $0.20 per text message for plans who do not have texting included in a plan. ‘TigerConnect’ is

a free mobile application that will be utilized for the project. After individuals send TigerConnect a one-time SMS containing a unique security code which costs approximately $0.05 to $0.20 once, you can receive unlimited text messages free of charge.

Will I be paid for my participation in this research?

To appreciate your time and effort participating in this research study, participants will receive a $10 gift card from the investigator after the completion of the 3-month project.

Informed Consent for Participation in a Research Study

Signature Block for Adult

By signing below, you agree that the above information has been explained to you and you have had the opportunity to ask questions. You understand that you may ask questions about any aspect of this research during the course of the study and in the future. Your signature documents your permission to take part in this research. Your signature documents your permission to take part in this research.

_____

Printed name of subject

_____ _____

Signature of subject Date

_____ _____

Signature of person obtaining consent Date

Request to Withdraw from a Research Study
(Please fill out all sections of the letter)

Name of Principal Investigator: _____

Title of Study: _____

IRB ID #: _____
(ID # can be found in the top right hand corner of your consent form)

I, _____want to end my participation in this study.
Name of Participant

Ending my participation means:

- I will no longer be contacted about this research study unless I need to be notified of a safety concern.
- Information about me, including my health information, will no longer be collected.

I understand that any data collected as part of my participation in the study will remain as part of the study records and cannot be removed.

_____ _____
Signature of Participant *Date*

_____
Date of Birth of Participant

20180531

Appendix H: Posters and Flyers

PARTICIPANTS NEEDED FOR RESEARCH IN DIABETES CARE

We are looking for volunteers to take part in a study of finding effects of diabetes **self-care education class with ongoing mobile technology support for adult type 2** diabetes patients in improving clinical outcomes, disease knowledge, and positive self-care practices.

In appreciation for your time, the investigator will give a $10 gift card to each participant after participation is complete.

To participate in this research, you must:

- Be 18 years or older
- Have Hemoglobin A1C level 7.5% or above
- Own a text message-capable mobile phone

As a participant in this study, you would be asked to:

- Answer questionnaires
- Do blood tests
- Attend 3 diabetes classes
- Receive weekly text messages
- Participate in monthly phone coaching
- Attend 2 face-to-face meetings

Your participation is **entirely voluntary** and would take up approximately three months of your time. By participating in this study, you will help us to understand the effectiveness of the program to improve patient-centered diabetes care and quality of care.

To learn more about this study, or to participate in this study, please contact the **Principal Investigator:**

Ji Min
Phone: 202-669-4455
Email: jimin@gwu.edu

This study is supervised by: Dr.A

SEEKING VOLUNTEERS FOR A RESEARCH STUDY

The purpose of this research study is to examine the effects of **diabetes self-care education class with ongoing mobile technology support for adult type 2 diabetes patients** in order to improve clinical outcomes, disease knowledge, and positive self-care practices.

To participate in this research, you must:

- Be 18 years or older
- Have Hemoglobin A1C level 7.5% or above
- Own a text message-capable mobile phone

Participation in this study involves:

- A time commitment of 3 months
- Answering questionnaires
- Doing blood tests
- Attending diabetes classes
- Receiving weekly text messages
- Monthly phone call coaching
- Attending 2 face-to-face meetings

In appreciation for your time, participants will receive a $10 gift card at the end of the study

To find out more information about this study, please contact Ji Min at:

- Phone: 202-669-4455
- Email: jimin@gwu.edu

Study Title: Mobile technology support for diabetes self-care activities

Principal Investigator: Ji Min

Research Study: Mobile technology support for diabetes self-care activities Contact: Ji Min #202-669-4455 jimin@gwu.edu